Recommendations

for Management of

DIABETES

IN VERMONT

Welcome to the fifth edition of the *Recommendations for Management of Diabetes in Vermont.* The Vermont Department of Health (VDH) contracts with The Vermont Program for Quality in Health Care (VPQHC) to produce this manual. This effort is a component of the Diabetes Prevention and Control Program in Vermont, a federally funded initiative coordinated by the VDH.

Updates have been made throughout the *Recommendations* with particular emphasis on prevention through self-management. Extensive revisions have occurred in the chapters relating to **Tobacco Cessation, Lipids, Self-Monitored Blood Glucose Testing** and **Medications**. We are also pleased to announce the addition of a chapter focusing on **Primary Prevention.**

We encourage providers to modify these *Recommendations* to meet the unique needs of each person with diabetes. These recommendations will be appropriate for treatment of most adults with diabetes most of the time, and the need for major modifications should not be common.

Healthy Vermonters 2010

Vermont Department of Health

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The Vermont Department of Banking, Insurance, Securities and Health Care Administration finds that *Recommendations for Management of Diabetes in Vermont* meets the Rule 10 standard that requires managed care organizations to develop or adopt, with appropriate clinical input, treatment protocols relevant to priority health care needs of their members. Rule 10 is a state regulation adopted in 1997 that establishes quality assurance standards and consumer protections for managed care plans.

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SUMMARY OF RECOMMENDATIONS

1) Hemoglobin A1C (A1C)

© The ADA suggests a target A1C <7 percent.

© The ADA recommends re-evaluation of the management plan for anyone unable to achieve desired goals.

© Measure A1C every three to six months.

2) Ophthalmic Exams

© *Type 1 diabetes*
Schedule yearly complete dilated and comprehensive eye examinations starting 3-5 years after diagnosis and/or at 10 years of age, whichever is later.

© *Type 2 diabetes*
Schedule yearly complete dilated and comprehensive eye examinations starting shortly after diagnosis.

© *Pregnant women with pre-existing type 1 or type 2 diabetes*
Schedule a first trimester examination with close follow-up during pregnancy and for one year postpartum.

© *Women with type 1 or type 2 diabetes who are planning pregnancies*
Schedule a complete dilated and comprehensive eye examination pre-conception,with counseling on the risk of development and/or progression of diabetic retinopathy.

© Cataracts and glaucoma are more common in people with diabetes.

3) Foot Exams, Ulcers and Infections

© Perform an annual comprehensive foot exam.

© Identify patients with high-risk feet.

© Closely monitor high-risk feet.

© Consider peripheral vascular studies in patients with signs or symptoms of vascular compromise.

© Ulcers should respond to treatment within a month.

© Treat foot infections aggressively.

4) Blood Pressure Measurement

© Measure blood pressure at every visit.

© The goal for blood pressure is less than 130/80 mmHg.

5) Renal Disease

© Screen urine for evidence of renal disease every year in both type 1 and type 2 diabetes.

© For patients with nephropathy, the major goals are to maintain BP < 130/80mmHg and to minimize proteinuria or albuminuria.

6) Lipid Management for Adults

© The primary treatment goal is an LDL<100 mg/dl both for people with known macrovascular disease and those without macrovascular disease.

© Obtain a fasting lipid profile annually for both type 1 and type 2 diabetes, more frequently if needed to achieve goals.

© If lipid values are low risk (LDL<100mg/dl, HDL>50mg/dl, and triglycerides<150mg/dl) repeat lipid profile every two years depending on CVD status.

© Consider statin therapy for all patients with diabetes over age 40 and a total cholesterol >135mg/dl, based on evidence from the Heart Protection Study.

7) Self-Management Education

© Diabetes self-management education involves a continuum of services ranging from the teaching of Survival Skills to Comprehensive Self-Management Education Programs to Intensive Management.

© Educational needs should be assessed at time of diagnosis and whenever there is poor clinical control or a major change in therapy.

© Licensed health care professionals with specific training in diabetes and training in education of people with diabetes should teach self-management education.

© Self-management education needs and plans should be documented in the medical record and acknowledged by all providers.

8) Medical Nutrition Therapy

© Medical Nutrition Therapy is an integral component of diabetes management and of diabetes self-management education.

© A registered dietitian (RD), certified in Vermont (CD) who is knowledgeable and skilled in implementing diabetes medical nutrition therapy should be the team member with primary responsibility for nutrition care and education.

9) Self-Monitored Blood Glucose Testing (SMBG)

© SMBG is an important tool for achieving glycemic control.

© The frequency of SMBG should be individualized based on type of diabetes, glucose goals, and other factors.

10) Tobacco Use Status and Counseling

© Screen at time of initial diabetes diagnosis

© Ask tobacco users about status of tobacco use at each visit.

© Advise every tobacco user to quit

© Assist every tobacco user who is willing to make a quit attempt access treatment.

© Follow up with every tobacco user at every visit.

11) Diabetes Mellitus And Exercise

© Exercise is an important therapeutic tool for people with diabetes.

© Exercise programs should be individualized to maximize benefit and minimize risk.

12) Obesity Treatment And Management For Type 2 Diabetes

© Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes.

© Weight loss and weight maintenance therapy should employ the combination of low-calorie diets, increased physical activity, and behavior therapy.

13) Immunization

© Annual influenza vaccine is recommended for all patients with diabetes.

© Pneumococcal vaccine is recommended for all patients with diabetes.

14) Screening For Type 2 Diabetes Mellitus

© Individuals who are at high-risk for type 2 diabetes should be screened for disease.

© A fasting plasma glucose test (FPG) is the simplest and least expensive screening test.

© A FPG result $\geq$ 126 mg/dl on two separate occasions is diagnostic of diabetes, values of 100-125 mg/dl are termed impaired fasting glucose, and values <100 mg/dl are considered normal.

© Individuals with impaired glucose tolerance, can significantly reduce the risk of developing type 2 diabetes through intervention with diet and exercise.

15) Gestational Diabetes Mellitus

© Prenatal screening for GDM is important; however, there is controversy about whether screening should be universal or selective.

© Women with GDM are at extremely high risk for developing type 2 diabetes later in life, and should be monitored closely.

16) Medications

© Medication Therapy can involve oral agents, insulin, or a combination of these two therapies.

© Medication Therapy is a therapeutic tool for use in lowering and maintaining blood glucose levels.

17) Intensive Insulin Management

© Candidates for Intensive Insulin Management must be motivated to improve glucose control and able to assume responsibility for their day-to-day care.

© Use of Intensive Insulin Management should be initiated, monitored and supported by a Comprehensive Diabetes Team.

© Intensive Insulin Management is essential during pregnancy and recommended for all who wish to reduce their risk of diabetes complications.

18) Psychosocial Issues in Diabetes Care

© Assess key psychosocial factors affecting chronic care.

© Choose appropriate behavioral strategies to enhance diabetes management.

19) Primary Prevention

© Counsel people at high risk for the development of diabetes on the benefits of moderate weight loss and exercise (weight loss of 5-7% with 150 minutes of exercise per week)

© Screen people at high risk

© Monitor people with pre-diabetes for the development of diabetes every 1-2 years

© Based on current knowledge, the American Diabetes Association (ADA) does not support the routine use of drug therapy in the prevention of Type 2 diabetes.

1) HEMOGLOBIN A1C (A1C)

- © The ADA recommends a target A1C <7 percent.
- © The ADA recommends re-evaluation of the management plan for anyone unable to achieve desired goals.
- © Measure A1C every three to six months.

What is A1C?

A1C is one of a group of stable minor hemoglobin components, glycated hemoglobin, formed slowly and nonenzymatically from hemoglobin and glucose. The rate of formation of A1C is directly proportional to the level of blood glucose. A single sample of blood contains red cells of various ages. Since the average life of a red cell is four months, a single A1C level reflects the blood sugar levels that red cells have been exposed to in the previous 2-3 months. Thus A1C levels reflect the average of a person's blood sugar levels in the past 2-3 months.

Certain clinical situations may alter the A1C level. Any clinical situation that increases erythrocyte turnover and increases the percentage of young circulating erythrocytes, such as a hemolytic anemia, will lower the measured A1C level. Other clinical situations may interfere with the assay methodology, e.g. hemoglobinopathies, chronic alcohol ingestion, salicylates, uremia and sample storage effects.

How often should an A1C be obtained?

The A1C level should be measured at least every 6 months in all persons with diabetes. More frequent monitoring is appropriate if a person's diabetes is not in control, if there are significant changes in management, and in some people with type 1 disease.

What assay does my lab use?

There are several different types of assays for glycated hemoglobin. Some assays measure A1C directly, others actually measure total glycated hemoglobin and derive a calculated A1C result. The range of normal varies between assay types. Clinicians should be aware of the specific assay used in their laboratory and the range of normal values. If a patient changes the laboratory that measures their A1C, the clinician should consider that the results may vary from previous results because of a change in methodology and/or a new range of normal and not because of a change in the patient's clinical status.

What is the goal for A1C?

The American Diabetes Association (ADA) recommends a goal A1C of <7 percent. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) is an ongoing study to test the risks and benefits of an A1C goal of <6 percent in people with type 2 diabetes. Based on this and other epidemiologic analyses, the ADA suggests that more stringent goals may be appropriate for individual patients in further reducing complications.

The American College of Endocrinology (ACE) and the American Association of Diabetes Educators (AADE) are recommending a target A1C of 6.5 percent. This rigorous target goal is consistent with goals currently in place in Europe.

Glycemic control markedly reduces the progression of microvascular complications. In the type 1 patients followed in the landmark Diabetes Control and Complications Trial, there was a 45 percent lower rate of progressive retinopathy in persons with a mean A1C of 8.2 percent as compared to patients with a mean A1C of 9 percent. Patients with a mean A1C of 7.2 percent had a rate of progressive retinopathy 33 percent lower than patients with a mean A1C of 8 percent. Glycemic control also delayed the onset and progression of renal disease and diabetic neuropathy.

The initial results of a major study of the effects of tight glycemic control in type 2 patients, the United Kingdom Prospective Diabetes Study (UKPDS), were published in 1998. The principal conclusions of that study to date are:

- Vigorous treatment of hyperglycemia decreases the morbidity and mortality of type 2 diabetes.
- Glycemic control reduces the risk of developing retinopathy, neuropathy and nephropathy. The overall rate of microvascular complications was 25 percent lower in the intensive therapy group than in the conventionally treated group.
- The use of insulin, sulfonylureas and metformin does not increase the risk of cardiovascular complications, thus there are no reasons not to treat glycemic levels aggressively.
- Control of blood pressure reduces the risk of both microvascular and macrovascular disease.
- The effects of glycemic control and blood pressure control are additive.
- The effect of tight glycemic control on reducing the risk of major cardiovascular events (myocardial infarction, stroke, amputation and sudden death) did not reach statistical significance, though patients with the highest levels of glycemia experienced a greater incidence in major events.

For individuals unable to achieve normal or near-normal glycemic goals (<7 percent) changes to the management plan should be considered. Changes to be considered are self-management education, alternative medications, rescheduling blood glucose monitoring, increasing patient contact, and referral to an endocrinologist.

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2) OPHTHALMIC EXAMS

- **Type 1 diabetes**
  schedule yearly complete dilated and comprehensive eye examinations starting 3-5 years after diagnosis and/or at 10 years of age, whichever is later.
- **Type 2 diabetes**
  schedule yearly complete dilated and comprehensive eye examinations at time of diagnosis.
- **Pregnant women with pre-existing type 1 or type 2 diabetes**
  schedule a first trimester examination with close follow-up during pregnancy and for one year postpartum.
- **Women with type 1 or type 2 diabetes who are planning pregnancies**
  schedule a complete dilated and comprehensive eye examination pre-conception, with counseling on the risk of development and/or progression of diabetic retinopathy.
- **Cataracts and glaucoma** are more common in people with diabetes.

Retinopathy

The prevalence of diabetic retinopathy is strongly correlated with the duration of the disease. After 20 years of diabetes, nearly all persons with type 1 disease and > 60 percent of persons with type 2 disease will have some retinopathy. Twenty-one percent of persons with type 2 disease will have retinopathy at the time of diagnosis.

Women who develop gestational diabetes are not at increased risk for diabetic retinopathy. However, if these women subsequently develop type 1 or type 2 disease, their retinopathy risk increases like anyone else's.

What patients are at highest risk for developing retinopathy?

Elevated A1C has been strongly correlated with increased risk for development of and progression of diabetic retinopathy. Poorly controlled systemic hypertension, proteinuria, and hyperlipidemia are all positively correlated with both the incidence and the rate of progression of retinopathy. Pregnancy and puberty may accelerate microvascular progression. Women with pre-existing diabetes who are planning a pregnancy should be counseled on the increased risk for development of and/or the progression of diabetic retinopathy.

Why is screening for retinopathy so important?

Patients with vision-threatening retinopathy may not have any symptoms. The retinal vascular complications of diabetes can result in permanent visual impairment. Laser photocoagulation therapy can limit further loss of vision in most patients with severe nonproliferative and proliferative retinopathy. Routine screening for the presence of retinopathy and monitoring of progression is a valuable strategy because of the potential silent presence of significant pathology and the availability of effective treatment.

What is the recommended screening exam for retinopathy?

Yearly dilated ophthalmoscopic examination is the best current approach to annual screening. Stereo fundus photography may be as sensitive, but this modality has not been completely evaluated for efficacy as a screening method and is not in widespread use.

Who should perform the screening exam?

The American Diabetes Association suggests that an Ophthalmologist or Optometrist with knowledge and experience in the diagnosis and management of diabetic retinopathy should perform the screening.

What screening results necessitate a referral to a retinal specialist?

Persons with clinically significant macular edema, moderate to severe nonproliferative retinopathy, or any proliferative retinopathy require the prompt care of an Ophthalmologist knowledgeable and experienced in the care of diabetic retinopathy.

Cataracts and Glaucoma

People with diabetes are at increased risk for the development of cataracts and glaucoma compared to people without diabetes. A dilated and comprehensive eye examination is the best current approach to annual screening.

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3) FOOT EXAMS, ULCERS AND INFECTIONS

- © Perform an annual comprehensive foot exam.
- © Identify patients with high-risk feet.
- © Closely monitor high-risk feet.
- © Consider peripheral vascular studies in patients with signs or symptoms of vascular compromise.
- © Ulcers should respond to treatment within a month.
- © Treat foot infections aggressively.

This chapter consists of four sets of recommendations:
1. Annual Comprehensive Foot Examination With Risk Stratification;
2. Vascular Evaluation of the Lower Extremity;
3. Management of Diabetic Foot Ulcers; and
4. Management of Diabetic Foot Infections.

1. Annual Comprehensive Foot Examination With Risk Stratification

The monograph, *Feet Can Last a Lifetime*, includes sample patient education materials, a 5.07 Semmes-Weinstein nylon monofilament, practice management tools, and a comprehensive resource list. (Copies of this monograph are available by contacting VPQHC). A brief summary of the recommendations follows:

Steps for Preventing Diabetes Foot Problems

1. Perform a Comprehensive Foot Exam Annually.

- Examine skin, hair, toenails, musculoskeletal structure, and evaluate vascular status, and protective sensation.
- Inspect footwear for proper fit, appropriate materials, foreign objects, torn linings, and proper cushioning.

2. Categorize Your Findings.

Low Risk	**Risk**
All of the following:	*One or more of the following:*
Intact protective sensation	Loss of protective sensation
Pedal pulses present	Absent pedal pulses
No foot deformity	Foot deformity
No history of foot ulcer	History of foot ulcer
No amputation	Prior amputation

3. Document Your Findings in the Medical Record.

4. Counsel Your Patients and/or Refer to a Diabetes Educator.

- Talk with your patients about their risk category.
- Demonstrate self-care techniques.
- Prescribe appropriate footwear.
- Give positive feedback for proper foot care.
- Give patients the self-care tip sheet in this kit.
- Counsel about smoking cessation if needed.
- Reinforce the importance of blood glucose control to reduce the risk for foot problems and other complications.

5. Follow up with Low Risk Patients.

- Visually inspect feet at subsequent visits as warranted.
- Inspect footwear at every visit as warranted.

6. Follow up with High Risk Patients.

- Place a "high risk feet" sticker on medical record.
- Visually inspect feet at every visit.
- Inspect footwear at every visit.
- Prescribe special inserts and shoes as needed.
- Refer to specialist for a risk factor you cannot rectify.
- Ensure that the elderly and blind have help for daily foot care.

2. Vascular Evaluation of the Lower Extremity in a Patient With Diabetes

This section contains additional specific information on the evaluation of the arterial supply to the lower extremities.

History

The patient should be asked about:

1. Calf, thigh or buttock claudication; and
2. Pain at rest in feet and toes (vascular rest pain is confined to the feet).

Physical Examination

Identify:

1. decreased or absent peripheral pulses i.e. femoral, popliteal, dorsalis pedis, posterior tibial;
2. cool feet;
3. dependent rubor;
4. atrophy of subcutaneous tissues; and
5. hair loss.

If there is any historical or physical suggestion of compromise of blood supply to the forefoot or toes, even with palpable pedal pulses, non-invasive peripheral vascular testing should be ordered.

Non-Invasive Peripheral Vascular Testing

An objective assessment of the severity of peripheral arterial occlusion can be obtained by the use of one or more non-invasive diagnostic tests. Non-invasive testing is also helpful in patients with an equivocal history or physical exam. Typically, a professional with expertise in the subject will work in conjunction with the referring practitioner to determine which tests are appropriate given the specific clinical scenario.

1. *Segmental measurement of blood pressure and Ankle: Brachial Index (ABI)*
   Serial placement of a blood pressure cuff and Doppler auscultation allows measurement of blood pressure along the legs. Normally, blood pressures in the legs and arms are equal. In fact, ankle pressure may be slightly higher than arm pressure. The ABI is the ratio of the arterial pressure in the ankle to that in the arm. The ABI in normal individuals is > 1.0. The ABI in individuals with moderate to severe occlusive disease is < 0.7. Additionally, a drop in blood pressure of 20mm Hg or more between levels indicates disease in that arterial segment. One of the pitfalls in patients with diabetes is that calcified vessels may give falsely elevated pressures.
2. *Pulse-Volume Recording (PVR)*
   Significant arterial occlusion decreases the normal volume displacement in the legs that occurs with each pulse and alters the waveform output of the test. Flat or barely pulsatile tracings at the ankle indicate moderately severe to severe ischemia. This test is commonly done with pressure measurements and provides supplemental information.
3. *Doppler Flow Velocity Waveform Analyses*
   The contour of the Doppler waveform is flattened with significant disease. This test gives similar information to the PVR.
4. *Treadmill Testing*
   Treadmill exercise testing allows assessment of functional limitation. Decline of the ABI after exercise supports the diagnosis of vascular occlusion if history and physical exam are equivocal. This test most frequently is used for patients with normal pulses who have symptoms of claudication to distinguish between vascular and neurogenic claudication.

Clinical Scenarios Using Non-Invasive Peripheral Vascular Testing
If there are any clinical signs or symptoms of peripheral vascular compromise, the patient should undergo non-invasive testing. An ABI of < 0.7 and flat or barely pulsatile PVR tracings at the ankle indicate moderately severe to severe ischemia. Treadmill testing may be helpful if initial results are normal at rest and the patient has a strong history of claudication.

If a patient is at high risk for foot problems but does not have signs or symptoms of vascular occlusion, consider ordering non-invasive testing to establish a baseline. Examples of high-risk foot conditions include the presence of abnormal foot structure or biomechanics, neuropathy, and employment that requires extensive walking or standing.

3. Management of Diabetic Foot Ulcers *(figure 1 on page 3-7)*

Ulcers should heal. There are three core therapies of diabetic ulcers:

1. Topical therapy;
2. Pressure reduction dressing; and
3. Edema reduction dressing.

Emerging technologies that may play a role include growth factors and artificial skin substitutes.

Surgical interventions are sometimes necessary, e.g. debridement, bone resection, arthrodesis, tendon lengthening and rerouting, and skin flaps.

The presence of an ulcer or the history of a previous ulcer should stimulate an evaluation of the underlying cause and appropriate preventive management. Specific consideration should be given to the possibility of previously undetected vascular compromise. *(figure 3-1)*

4. Management of Diabetic Foot Infections *(figure 2 on page 3-8)*

All patients with diabetes should be proactively encouraged to seek early evaluation at the first suggestion of infection.

Pain and tenderness are not consistent findings and should not be used to judge the presence of infection nor be used to judge progress of treatment.

Infection Classification
Severity of infection is based on clinical exam:

Type I (mild) infections are characterized by mild erythema of skin, minimal edema, and only minor breaks in the skin, e.g. superficial ulcer, small laceration, blister. There is no osteomyelitis nor systemic toxicity.

Type II (moderate, limb threatening) infections usually surround a chronic ulcer. Ulceration extends to deep tissues, but no bone is exposed. Edema may extend to the forefoot. Cellulitis is typically present. Purulent drainage and osteomyelitis may be present.

Type III (severe, limb and life threatening) infections are typically odorous and draining purulent material. Erythema, cellulitis, and lymphatic streaking are typical. There may be gangrenous, wet, black soft tissue present. Bone or joint space may be exposed. Osteomyelitis may be present. Signs and symptoms of systemic toxicity may be present.

Diagnosis

Physical Exam

- Probe bone for soft areas suggestive of osteomyelitis.
- Probe wound for tracking and undermining.
- Document wound area and depth.
- Periodically evaluate wound size and volume to gauge response to therapy.

Pain and tenderness are not consistent findings. Practitioners unfamiliar with wound probing should consult with someone with training and experience with this assessment.

Laboratory

- Culture purulent drainage, abscesses and tissue from deep debridement.
- Do not culture superficial lesions as these results are not particularly helpful.
- Blood cultures are appropriate in serious infections.

CBC in Type II and III infections

- Renal and liver function tests if needed to guide antibiotic choice.

Radiology

- Acute osteomyelitis is not identifiable by routine radiographs or CT scans, except in the late phases.
- Plain radiographs may reveal soft tissue gas in deep infections.
- Serial radiographs aid monitoring erosive changes in chronic lesions, and are the most useful.
- Bone scans are rarely helpful in making the diagnosis of osteomyelitis.
- Bone scans are helpful in detecting a Charcot fracture as the cause of an acutely swollen foot with no open lesion.

Treatment

Type I infections with no evidence of peripheral vascular obstruction may be treated with outpatient oral antibiotics. The most likely organisms are Staphylococcus or Streptococcus. Patients should be seen again in 24-48 hours. If there is no improvement within 48 hours, hospital admission is indicated for bed rest, wound care, and intravenous antibiotics. If the patient has peripheral vascular disease, initial hospitalization and surgical consultation are recommended. Consultation with podiatry is appropriate if underlying deformity or altered biomechanics are present.

If there is no response to therapy or re-infection occurs, one should re-evaluate vascular supply, wound care, and antibiotic therapy. Consultation with an expert in the management of diabetic foot infection is also appropriate.

Type II infections necessitate in-hospital intravenous antibiotic therapy. Surgical consultation is indicated for drainage, debridement and culture. Infectious disease consultation is appropriate. Type II and III infections are typically polymicrobial (gram negative rods, anaerobes and enterococci).

Type III infections are a surgical emergency. Immediate surgical drainage and/or amputation is necessary. Infectious disease consultation is appropriate. Type II and III infections are typically polymicrobial (gram negative rods, anaerobes and enterococci).

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figure 1

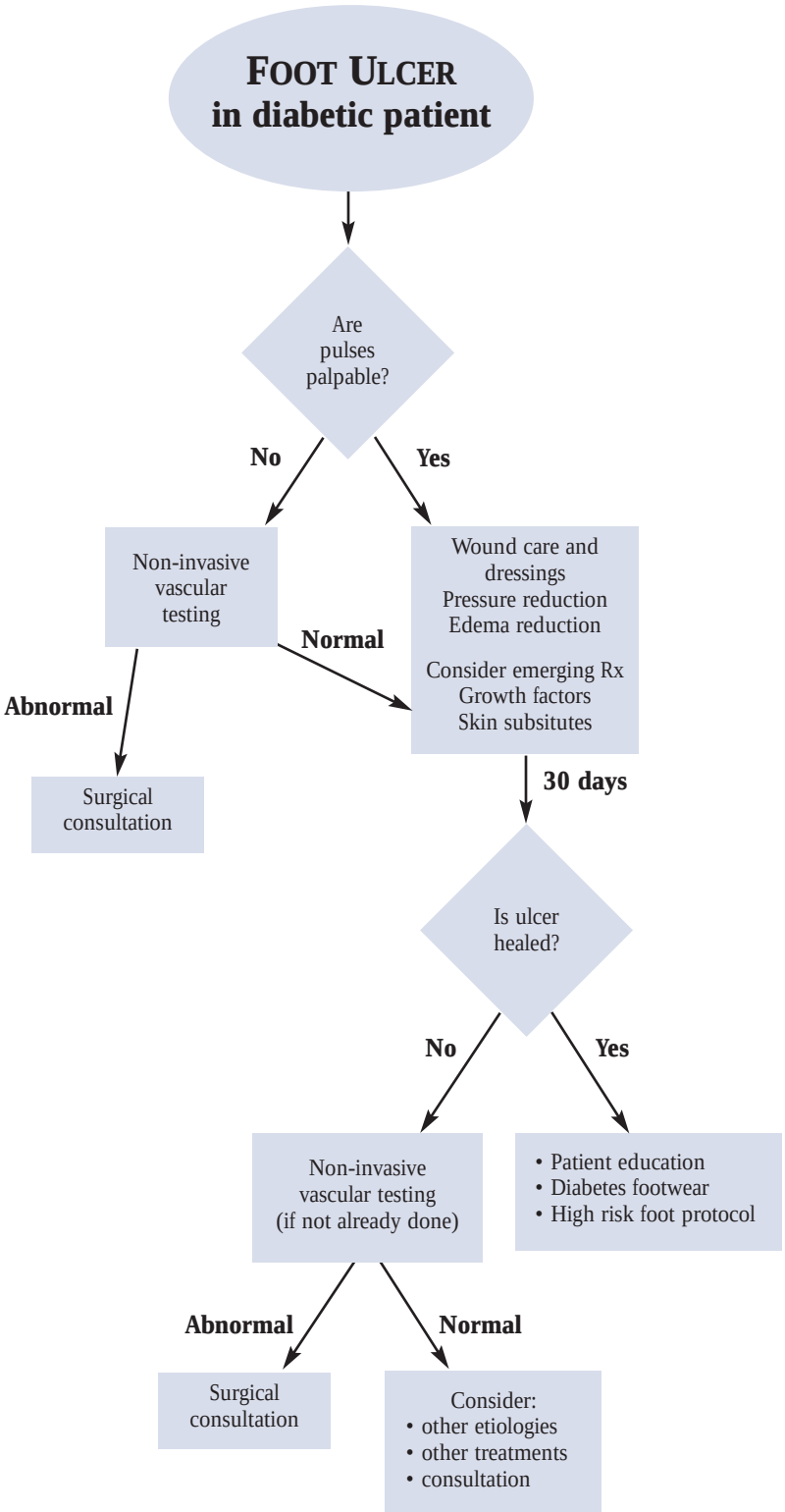
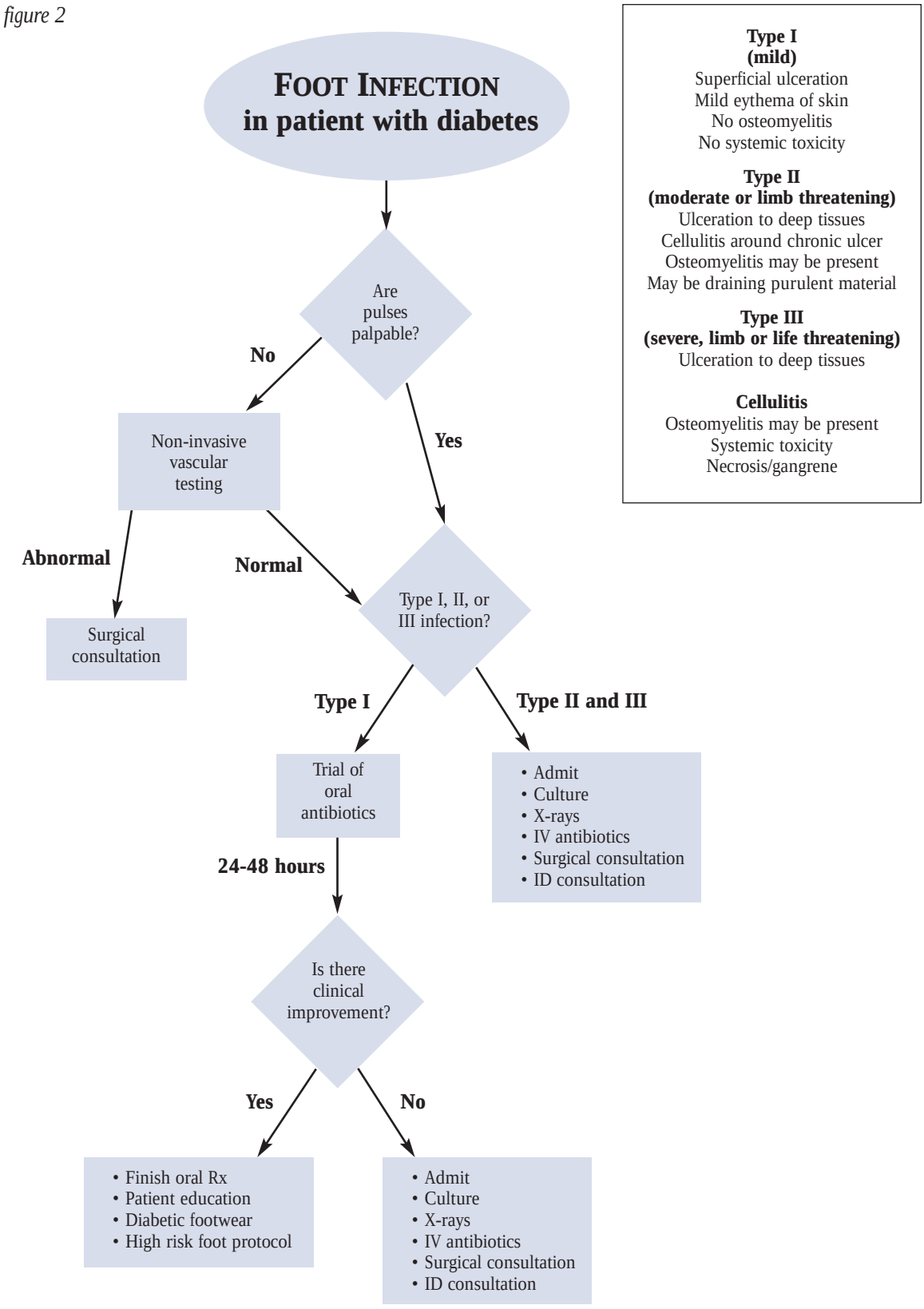

FOOT ULCER
in diabetic patient
Are pulses palpable?
No
Yes
Non-invasive vascular testing
Wound care and dressings
Pressure reduction
Edema reduction
Consider emerging Rx
Growth factors
Skin subsitutes
Normal
Abnormal
Surgical consultation
30 days
Is ulcer healed?
No
Yes
Non-invasive vascular testing (if not already done)
• Patient education
• Diabetes footwear
• High risk foot protocol
Abnormal
Normal
Surgical consultation
Consider:
• other etiologies
• other treatments
• consultation

figure 2


FOOT INFECTION
in patient with diabetes
Are pulses palpable?
No
Yes
Non-invasive vascular testing
Abnormal
Normal
Surgical consultation
Type I, II, or III infection?
Type I
Type II and III
Trial of oral antibiotics
• Admit
• Culture
• X-rays
• IV antibiotics
• Surgical consultation
• ID consultation
24-48 hours
Is there clinical improvement?
Yes
No
• Finish oral Rx
• Patient education
• Diabetic footwear
• High risk foot protocol
• Admit
• Culture
• X-rays
• IV antibiotics
• Surgical consultation
• ID consultation
Type I
(mild)
Superficial ulceration
Mild eythema of skin
No osteomyelitis
No systemic toxicity
Type II
(moderate or limb threatening)
Ulceration to deep tissues
Cellulitis around chronic ulcer
Osteomyelitis may be present
May be draining purulent material
Type III
(severe, limb or life threatening)
Ulceration to deep tissues
Cellulitis
Osteomyelitis may be present
Systemic toxicity
Necrosis/gangrene

4) BLOOD PRESSURE MEASUREMENT

- © Measure blood pressure at every visit.
- © The goal for blood pressure is less than 130/80 mmHg.

Why is control of blood pressure important?

Hypertension contributes to the development and progression of chronic diabetic complications. Control of hypertension reduces the rate of progression of diabetic nephropathy and reduces the complications of hypertensive nephropathy, cerebrovascular and cardiovascular disease.

Antihypertensive treatment has been shown to decrease the mortality rate by 9 to 43 percent in the first 16 years after the development of diabetic nephropathy. The need for dialysis and transplantation was reduced from 73 to 31 percent of patients in the same period.

In type 1 diabetes, persistent hypertension is often a manifestation of diabetic nephropathy. In type 2 diabetes, hypertension often is part of the Metabolic Syndrome which includes glucose intolerance, insulin resistance, obesity, dyslipidemia, and coronary artery disease. Isolated systolic hypertension may occur in both types of diabetes and is due, in part, to inelasticity of atherosclerotic blood vessels.

What are appropriate treatments for high blood pressure in someone with diabetes?

Lifestyle modifications

Lifestyle modifications are the first therapy to be employed to treat hypertension, unless the need to reduce the level of hypertension is urgent. However, lifestyle and behavioral therapy alone should be attemped for no longer than three months before reevaluation of the treatment plan. Lifestyle modifications include:

- weight loss,
- exercise,
- reduction of dietary sodium,
- limiting alcohol consumption,
- smoking cessation,
- increased consumption of fruits, vegetables and lowfat dairy products.

A systolic blood pressure >160 mmHg, and/or a diastolic blood pressure > 100 mmHg mandates immediate pharmacological therapy. Drug therapy should begin with a drug class demonstrated to reduce cardiovascular events in patients with diabetes.

ACEI (angiotensin converting enzyme inhibitors)/ARBs (angiotensin II receptor blockers)
In patients with microalbuminuria or clinical proteinuria, ACEI and ARBs are indicated as part of the initial treatment plan. ACEIs improve cardiovascular outcomes for high risk patients with or without hypertension. ACEIs offer improved outcomes for patients with congestive heart failure. ACEIs and ARBs have an additional benefit to patients with diabetes in that they decrease the rate of progression of renal disease beyond what would be predicted by controlling their hypertension.

Additional Pharmacologic Treatment
If after 6 to 8 weeks of initial treatment, blood pressure goals have not been reached, additional pharmacological treatment is indicated. Medications should be added in a stepwise fashion. Concomitant disease should be considered when choosing medications, e.g. fluid overload, vascular disease. Information or advice about medications or treatment strategies for hypertension is available from a physician experienced in the care of patients with diabetes and renal disease.

Lowering the blood pressure with antihypertensive drug regimens which include ACEIs, ARBS, beta-blockers, diuretics, and calcium channel blockers has been shown to be effective for reducing cardiovascular events. ACEIs, ARBs, calcium channel blockers and low dose diuretics are associated with fewer adverse effects on glycemic control and lipid profiles and renal function than other anti-hypertension medications.

What are treatment goals for isolated systolic blood pressure in someone with diabetes?

Elevated systolic BP is a more important CV risk factor than elevated diastolic BP in persons over the age of 50 years. Control of isolated systolic BP reduces total mortality, CV mortality and stroke. The goal is a blood pressure < 140 mmHg for all patients and less than 130 mmHg in those with diabetes or renal disease.

1. Diabetic Nephropathy, *Diabetes Care*, Volume 27, Supplement 1, January 2004: pps S79-S83. (as noted in the sixth report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure).
2. Standards of Medical Care in Diabetes, *Diabetes Care,* Volume 27, Supplement 1, January 2004: pps S15-S35.
3. Hypertension Management in Adults with Diabetes, *Diabetes Care,* Volume 27, Supplement 1, January 2004: pps S65-S67.
4. Seventh report of the joint national committee on prevention, detection, evaluation, and treatment of high blood pressure http://www.hypertensionaha.org.

5) RENAL DISEASE

- © Screen urine for evidence of renal disease every year in both type 1 and type 2 diabetes.
- © For patients with nephropathy, the major goals are to maintain BP < 130/80 mmHg and to minimize proteinuria or albuminuria.

Screening for diabetic renal disease

The first clinical evidence of diabetic nephropathy is the appearance of a small excess amount of albumin in the urine termed *microalbuminuria* (> 30 mg albumin excretion per day). Persons with microalbuminuria are referred to as having *incipient nephropathy* and are likely to progress to clinical proteinuria and decreasing renal function over a period of years.

Clinical proteinuria is defined as > 300 mg of protein excretion per day. Persons with clinical proteinuria are referred to as having overt nephropathy. Once clinical proteinuria occurs, the risk of progression to end-stage renal disease (ESRD) is high in both type 1 and type 2 disease.

Additionally, microalbuminuria is a marker for increased cardiovascular risk, and, if present, is an indication for screening for vascular disease and aggressive intervention to reduce other cardiovascular risk factors, e.g., dyslipidemia, smoking, inactivity.

When should screening begin?

Because renal disease rarely develops in short duration type 1 diabetes, screening in persons with type 1 diabetes should start with the beginning of puberty or after five years from the initial diagnosis.

Because of the difficulty in precise dating of the onset of type 2 diabetes, screening should start at the time of diagnosis.

What screening tests should be used?

The initial screening test in all adult patients is a routine urinalysis because some patients will already have clinical proteinuria (> 300 mg/day), which is detectable by routine urinalysis. If the routine urinalysis is positive for protein, a quantitative measure of the amount of proteinuria is indicated. Such measures include spot or 24-hour collection for urinary protein/creatinine ratio.

If the urinalysis is negative, a test for the presence of microalbuminuria is indicated. Two screening methods are available:

1. albumin/creatinine ratio in a single urine sample
2. 24 hour urine collection for albumin and creatinine

First void or morning samples are preferred for the single urine sample technique. If this timing is not possible, all samples for a given individual should be collected at the same time of day to minimize the effect of normal diurnal variation in albumin excretion.

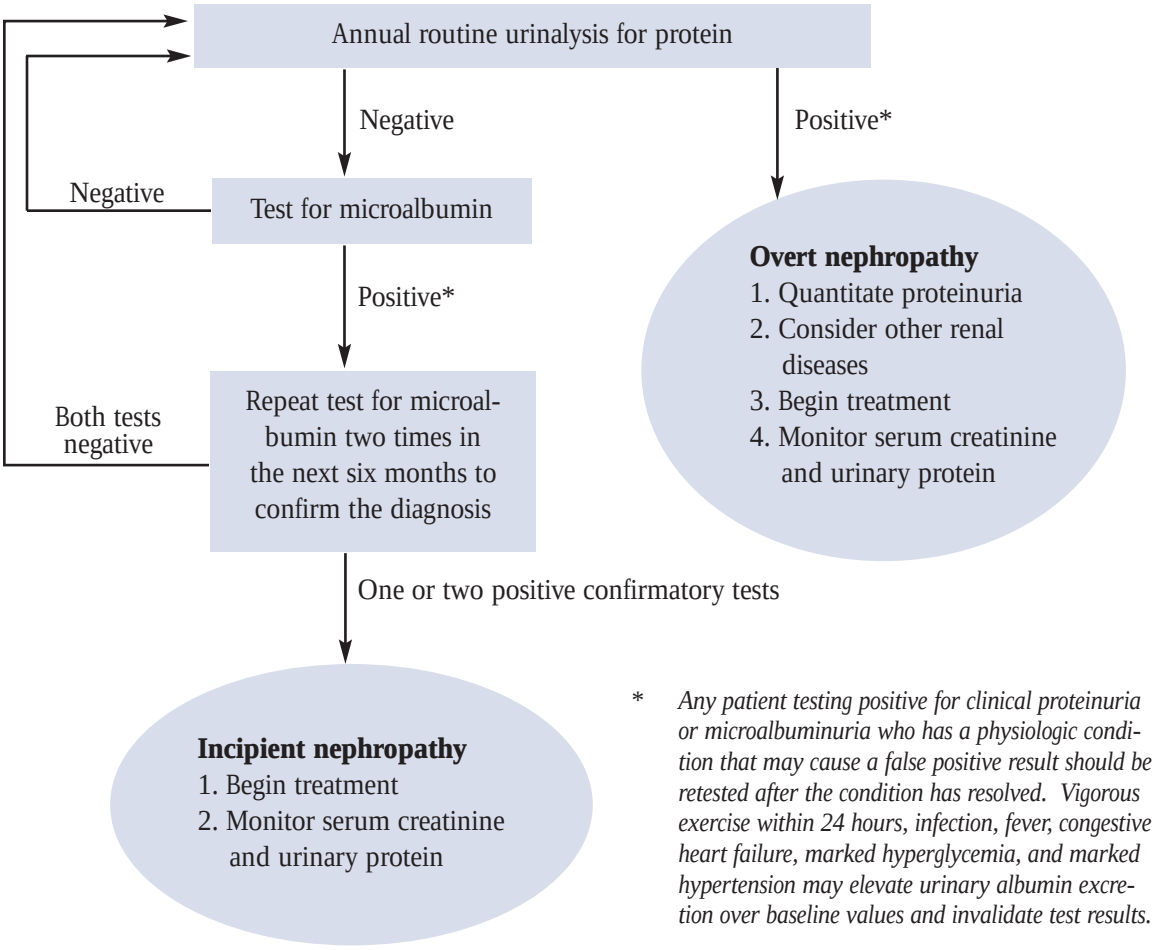
Specific assays are required to detect microalbuminuria; routine urinalysis and other standard assays for protein are not sufficiently sensitive. Screening with reagent tablets or dipsticks specific for microalbuminuria are 95 percent sensitive and 93 percent specific. However, because tests by reagent tablets or dipsticks are subject to error from alterations in urine concentration, all positive results should be confirmed by one of the three more specific methods mentioned above.

Because there is day-to-day variability in albumin excretion, at least two of three collections done in a three to six month period should show elevated levels before the diagnosis of incipient nephropathy is made.

The recommendations for screening for renal disease are summarized in the following algorithm.

Figure 5-1

Screening for Renal Disease



* *Any patient testing positive for clinical proteinuria or microalbuminuria who has a physiologic condition that may cause a false positive result should be retested after the condition has resolved. Vigorous exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, and marked hypertension may elevate urinary albumin excretion over baseline values and invalidate test results.*

Categorization of abnormalities in albumin and protein excretion

Table 5-1

Category	Spot collection	24-h collection	Timed collection
Normal	<30 µg albumin/mg creatinine	<30 mg albumin/24 h	<20 µg albumin/min
Microalbuminuria	30-299 µg albumin/mg creatinine	30-299 mg albumin/24 h	20-199 µg albumin/min
Clinical proteinuria*	≥300 µg protein/mg creatinine*	≥300 mg protein/24 h	≥200 µg protein/min

**Once clinical proteinuria is detected, teasing out that portion of total protein that is albumin adds no useful information.*

Treatment options and goals for patients with diabetic nephropathy

Facts

- Achieving normoglycemia will decrease the rate of progression to overt nephropathy.
- Lowering blood pressure will retard the development of overt nephropathy and decrease its rate of progression.
- Angiotension converting enzyme inhibitors (ACEIs) or Angiotensin II receptor blockers (ARBs) will decrease the level of albuminuria/proteinuria and the rate of progression to ESRD.

Options

- ACEIs are indicated in all type 1 patients with microalbuminuria even if they are normotensive. Use of ACEIs in normotensive type 2 patients with microalbuminuria is less substantiated by studies. If a type 2 patient has progression in the amount of albuminuria or develops hypertension, ACEI or ARB treatment then becomes clearly indicated.
- Combinations of ACEIs and ARBs are effective for decreasing BP and proteinuria.
- Protein restriction to < 0.8 grams/kg/day is not recommended. Further restriction can be considered in patients with advancing renal dysfunction, symptomatic uremia or in consultation with a physician experienced in the care of patients with renal disease.
- Smoking cessation is beneficial for renal function in diabetic patients. There is substantial evidence for the adverse effect of smoking on renal functional deterioration in both type 1 and type 2 diabetes.

Goals

- The major goal is to maintain BP < 130/80mmHg.
- Serum creatinine and urinary protein excretion should be measured every 3-6 months until stable and then annually. Urinary protein excretion should be measured as an albumin/creatinine ratio in a patient with incipient nephropathy and as a protein/creatinine ratio in a patient with overt nephropathy.

Goals have not been established for the amount of albuminuria in patients with incipient nephropathy or the amount of proteinuria in patients with overt nephropathy. Expert opinion is that less albuminuria or proteinuria is better. The committee members suggest the following goals:

- For patients with incipient nephropathy (microalbuminuria), the goal of treatment is to stabilize or reduce the urinary albumin /creatinine ratio.
- For patients with overt nephropathy (clinical proteinuria), the goal of treatment is to maintain or reduce the urinary protein /creatinine ratio to < 0.5.

Currently available therapy does not necessarily ensure that even these goals can be achieved.

1. Nephropathy in Diabetes. American Diabetes Association, *Diabetes Care* Volume 27, Supplement 1, January 2004; pps S79-S83.
2. Laverman, G.D., Remuzzi, G., Ruggenti, P., ACE inhibition versus angiotensin receptor blockade: which is better for renal and cardiovascular protection? *JASN* 15 S64-S70, 2004.
3. Thurman, J.M. and R.W. Schrier, Comparative effects of Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers on blood pressure and the kidney, *Am. J. Med*. 2003; 114:588-598.
3. Orth et al, Renal Risks of Smoking, *Kidney International*, Vol. 51 (1997), pps 1669-1677.

6) LIPID MANAGEMENT FOR ADULTS

- © The primary treatment goal is an LDL <100 mg/dl both for people with known macrovascular disease and those without macrovascular disease.
- © Obtain a fasting lipid profile annually for both type 1 and type 2 diabetes, more frequently if needed to achieve goals.
- © If lipid values are low risk (LDL <100mg/dl, HDL>50mg/dl, and triglycerides<150mg/dl) repeat lipid profile every 2 years depending on CVD status.
- © Consider statin therapy for all patients with diabetes over age 40 and a total cholesterol >135mg/dl, based on evidence from the Heart Protection Study.

Why is control of lipid abnormalities important?

Diabetes is one of the major risk factors for vascular disease, along with smoking, dyslipidemia, hypertension, and a family history of premature coronary heart disease. In type 2 diabetes there is an increased risk for obesity and lipid abnormalities that is independent of glycemic control. Because of the 2- to 4-fold increase in the prevalence of vascular disease in persons with diabetes, it is important to identify and manage all modifiable cardiovascular risk factors. The goal of lipid management is to prevent the development or progression of vascular disease.

What is the relationship between levels of blood lipids and the risk of coronary heart disease?

The most common pattern of dyslipidemia in patients with type 2 diabetes is an elevated triglyceride level and decreased HDL cholesterol level. The mean concentration of LDL cholesterol in people with type 2 diabetes is not significantly different from individuals who do not have diabetes. However, qualitative changes in LDL may be present.

Previous evidence in support of lipid lowering therapy is available from the Scandinavian Simvistatin Survival Study (4S study), the Cholesterol and Recurrent Events Study (CARE Study) and the Helsinki Heart Study. The 4S and CARE studies provide evidence that pharmacologic therapy with statin drugs (HMG co-A reductase inhibitors) reduce CHD events (and mortality in 4S) in diabetic subjects with known CHD.

The Heart Protection Study, published in 2003, provides the best direct evidence that statin therapy reduces CHD events in diabetic subjects regardless of baseline lipid levels. Almost 6000 patients with diabetes age >40 years and with total cholesterol >135mg/dl were assigned to 40 mg of simvastatin or placebo for an average of 4.8 years. Simvastatin lowered CHD events by 22% with an absolute risk reduction of 5% and an NNT of 20. The risk reduction was similar across all LDL subgroups, including patients with baseline LDL values <116mg/dl (<3mmol/L).

What diagnostic tests for hyperlipidemia are appropriate?

Adult patients should be evaluated annually or more frequently if needed to achieve goals. Testing should include:

- fasting total cholesterol,
- fasting triglyceride,
- HDL cholesterol,
- calculated LDL cholesterol.

If all values are normal, less frequent testing may be appropriate. If the lipid profile is abnormal, consideration should be given to correctable secondary causes such as hypothyroidism (which has an increased prevalence in people with diabetes), poor glycemic control, medications (i.e. thiazides, steroids), and alcohol consumption.

What are the treatment goals for hyperlipidemia in persons with diabetes?

The first goal of therapy is to reduce LDL concentrations to <100mg/dl. The next priorities are to lower triglycerides to <150mg/dl and raise HDL to >40mg/dl in men and >50mg/dl in women.

What are the priorities for management of lipid abnormalities in people with diabetes?

In general, all people with diabetes who have lipid abnormalities should have a trial of nutrition therapy, exercise, and optimization of glycemic control. Initial pharmacologic therapy should be with a statin. With the evidence from the Heart Protection Study, patients with diabetes over the age of 40 with a total cholesterol >130mg/dl, should be considered for statin therapy, regardless of LDL level.

Combination therapy with statins and fibrates or niacin may be necessary to achieve lipid targets, but has not been evaluated in outcomes studies for either event reduction or safety.

For people with diabetes who have clinical CVD and an LDL value >100mg/dl, pharmacological intervention should be started at the same time as lifestyle intervention is initiated.

1. Dyslipidemia Management in Adults With Diabetes. *Diabetes Care* 2004; Volume 27, Supplement 1, January 2004; pps S68-S71. http://care.diabetesjournals.org/content/vol27/suppl_1/
2. Executive Summary of the Third Report of the National Cholesterol Education Program Expert Panel on the Detection, *Evaluation and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel III). JAMA 2001; 285:2486-2497. http://www.nhlbi.nih.gov/guidelines/cholesterol/
3. Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in 5963 people with diabetes: an RCT. Lancet 2003; 361:2005-2016.

7) SELF-MANAGEMENT EDUCATION

- © Diabetes self-management education involves a continuum of services ranging from the teaching of Survival Skills to Comprehensive Self-Management Education Programs to Intensive Management.
- © Educational needs should be assessed at time of diagnosis and whenever there is poor clinical control or a major change in therapy.
- © Licensed health care professionals with specific training in diabetes and training in education of people with diabetes should teach self-management education.
- © Self-management education needs and plans should be documented in the medical record and acknowledged by all providers.

As of September 30, 1998, all health insurance policies in Vermont, including Medicaid, are required to provide coverage for self-management training and education for individuals with diabetes if prescribed by a health care professional legally authorized to prescribe such items under law.

What are Survival Skills?

Survival Skills should be offered to all persons with diabetes at the time of diagnosis. Ideally, all people with diabetes would be able to complete a Comprehensive Self-Management Education Program. Those people unable to attend a Comprehensive Program should receive instruction in the following key areas:

1. Disease basics
2. Self-monitoring of blood glucose
3. Exercise and activity
4. Medication use
5. Hypoglycemia/Hyperglycemia
6. Nutrition

Survival Skills should be taught by a licensed health care professional with specific training in diabetes and the education of people with diabetes. Specific training must be consistent with the prevailing state standards.

What is a Comprehensive Self-Management Education Program?

A Comprehensive Self-Management Education Program is an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). This process includes assessment of the individual's specific education needs; identification of the individual's specific diabetes self-management goals; education and behavioral intervention directed toward helping the individual achieve identified self-management goals; and, evaluation of the individual's attainment of identified self-management goals. The National Standards of Diabetes Self-Management Education identify 10 core educational content areas. Assessed needs of the individual will determine which areas listed below are delivered.

1. Describing the diabetes disease process and treatment options
2. Incorporating appropriate nutritional management
3. Incorporating physical activity into lifestyle
4. Utilizing medications (if applicable) for therapeutic effectiveness
5. Monitoring blood glucose, urine ketones (when appropriate), and using the results to improve control
6. Preventing, detecting, and treating acute complications
7. Preventing (through risk reduction behavior), detecting, and treating chronic complications
8. Goal setting to promote health and problem solving for daily living
9. Integrating psychosocial adjustment to daily life
10. Promoting preconception care, management during pregnancy, and gestational diabetes management (if applicable)

A designated program coordinator manages the program. The coordinator is responsible for program planning, implementation, and evaluation. The coordinator must be either a Certified Diabetes Educator (CDE) or a health care professional who has completed at least 24 hours of approved education on diabetes, educational principles and behavioral strategies.

Program instructors perform much of the teaching. Program instructors must be licensed health care professionals. They must either be a CDE or have completed at least 16 hours of education on diabetes, educational principles, and behavioral strategies.

All comprehensive program staff need to obtain a minimum of 7.5 to 15 continuing education units per year.

For a list of ADA recognized Diabetes Self-Management Education programs go to www.diabetes.org.

How often should educational needs be assessed?

Educational needs should be assessed at the time of diagnosis and subsequently reassessed at least every five years. Reassessment of educational needs should also occur whenever there is poor clinical control or a major change in therapy.

What is a comprehensive educational assessment?

Diabetes is a complex disease that affects nearly every aspect of a person's life. A comprehensive assessment of a person's educational needs is likewise complex. The American Association of Diabetes Educators has identified the following twelve components of a comprehensive educational assessment:

1. Health history
2. Medical history
3. Previous use of medication

4. Diet history
5. Current mental health status
6. Family and social supports
7. Previous diabetes education, actual knowledge, and skills
8. Current self-care management practices
9. Use of healthcare delivery systems
10. Lifestyle practices
11. Physical and psychosocial factors
12. Factors that influence learning

Preferably a team consisting of a registered dietitian and a registered nurse should conduct the initial assessment and all reassessments. Both dietitian and nurse should be Certified Diabetes Educators or licensed health care professionals with specific training in diabetes and the education of people with diabetes.

What is Intensive Management Education?

Intensive management education may be either individual or special group sessions designed for patients who are initiating continuous subcutaneous insulin infusion or multiple daily injection therapy combined with carbohydrate counting. A diabetes treatment team familiar with the use of the insulin pump and intensive management coordinates these sessions. This planned education is an integral component of care.

Who is a Certified Diabetes Educator (CDE)?

A Certified Diabetes Educator is a health care professional who is qualified by the National Certification Board for Diabetes Educators to teach people with diabetes how to manage their condition. To achieve certification, the individual must have accrued 1000 hours in direct diabetes education and passed the certification exam of the National Certification Board for Diabetes Educators. To maintain a CDE without retaking the exam, educators must obtain a minimum of 15 continuing education units per year.

For more information about Certification as a Diabetes Educator, go to the National Certification Board for Diabetes Educators at www.ncbde.org.

1. American Diabetes Association, *Diabetes Care* 23:682-689, 2000.
2. American Association Diabetes Educators: *Member Resource Guide* (position statement)
The 1999 Scope of Practice for Diabetes Educators and the Standards of Practice for Diabetes Educators, 2000.

8) MEDICAL NUTRITION THERAPY (MNT)

- © Medical Nutrition Therapy is an integral component of diabetes management and of diabetes self management education.
- © A registered dietitian (RD), certified in Vermont (CD) who is knowledgeable and skilled in implementing diabetes medical nutrition therapy should be the team member with primary responsibility for nutrition care and education.

What is Medical Nutrition Therapy?

MNT consists of nutrition assessment and the development of an individualized nutrition prescription based on treatment goals. Individualized MNT takes into account age, weight, lifestyle and other related medical, social or psychological conditions.

Patient participation and sensitivity to cultural, ethnic and financial considerations are of prime importance when seeking to facilitate adherence.

What are the goals of Medical Nutrition Therapy?

The primary goals of MNT are to help:

- Maintain blood glucose levels in the normal range or as close to normal as is safely possible to prevent or reduce the risk for complications of diabetes.
- Maintain blood lipid levels that reduce the risk for macrovascular disease.
- Maintain blood pressure levels that reduce the risk for vascular disease.
- Provide adequate calories for maintaining or attaining a reasonable body weight goal, and for normal growth and development in children.
- Improve health through healthy food choices and physical activity.
- Prevent and treat the acute complications of insulin-treated diabetes such as hypoglycemia, and blood glucose changes that occur during short-term illness and exercise.
- Prevent and treat the long-term complications of diabetes such as renal disease, neuropathy, retinopathy, hypertension and cardiovascular disease.

What are the components of a nutrition prescription/meal plan?

The key components of a nutrition prescription are:

- Calories based on individual needs and weight management goals.
- Carbohydrate and monounsaturated fat together should provide 60-70 percent of energy intake.

- Protein should provide 10-20 percent of total energy intake. Recent evidence suggests that it may be prudent for people with diabetes not to consume protein in excess of 20 percent of total energy intake.
- Saturated fat should be limited to < 10 percent of total energy intake.

What are the recommended number of nutrition therapy visits for someone with type 1 diabetes?

In the first three months after diagnosis, three to four appointments with a registered dietitian are recommended for someone with type 1 diabetes. Follow-up care should include four routine follow-up visits per year with dietitian.

What are the recommended number of nutrition therapy visits for someone with type 2 diabetes?

Up to four routine visits per year with a registered dietitian are recommended for someone with type 2 diabetes..

1. Nutrition Principles and Recommendations in Diabetes.. *Diabetes Care,* Volume 27, Supplement 1, January 2004; pps S36-S46.
2. *Medical Nutrition Therapy Across the Continuum of Care*, The American Dietetic Association, 1996.
3. Pastors, JG, et al. *Diabetes Nutrition Q &A for Health Professionals,* American Diabetes Association, 2004.

9) SELF-MONITORED BLOOD GLUCOSE TESTING (SMBG)

- © SMBG is an important tool for achieving glycemic control.
- © The frequency of SMBG should be individualized based on type of diabetes, glucose goals, and other factors.

Why is SMBG important?

Self-monitoring of blood glucose allows persons with diabetes to achieve very specific glycemic goals. Maintenance of normal or near-normal blood glucose levels has major health benefits for persons with diabetes. Results of the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) indicate that there is a direct relationship between blood glucose level and the risk of future diabetes related complications (diabetic retinopathy, nephropathy, and neuropathy). Both the development and the progression of microvascular complications are slowed with improved glucose control.

How many times a day should SMBG be done?

Persons with type 1 diabetes should be encouraged to use SMBG for routine daily monitoring. For most persons with type 1 diabetes SMBG is recommended 3 or more times a day. Frequency and timing of SMBG should be tailored to meet individual needs and goals.

The optimal frequency of SMBG in persons with type 2 diabetes is not known but should be sufficient to facilitate attaining treatment goals. Times may include fasting, pre-prandial and post-prandial. Varying the times may give a better picture of overall glucose control. In individuals whose pre-prandial glucose values are within target range but whose A1C levels remain high, monitoring of post-prandial glucose levels may be helpful. Monitoring post-prandial glucose values and choosing treatments focused on maintaining these levels < 180mg/dl may help lower A1C.

The American Diabetes Association (ADA) suggests SMBG for all patients being treated with insulin, or sulfonylureas, and for all patients who are not achieving their glycemic goals. Daily SMBG is especially important for patients treated with insulin or sulfonylureas to prevent asymptomatic hypoglycemia. For both type 1 and type 2 diabetes, testing should occur more frequently when modifying therapy. It is the ADA's recommendation that efforts should be made to substantially increase the appropriate use of SMBG.

(For Recommendations for SMBG in gestational diabetes see section 15.)

How accurate are SMBG measurements?

Each patient's ability to properly use monitoring equipment needs to be evaluated by health practitioners at regular intervals to assure accuracy.

It is important for people with diabetes to know whether their monitor provides whole blood or plasma calibrated results. Plasma glucose values are 10 – 15% higher than whole blood glucose values. It is important that persons with diabetes be given individualized goals for glucose control.

A recent study found that forearm results may vary significantly from fingerstick results and that fingerstick measurements should always be used to confirm a forearm test that is not consistent with how the patient feels.

What about continuous blood glucose monitoring?

There is a glucose sensor system available, which allows for continuous ambulatory blood glucose monitoring. Specialized diabetes centers in Vermont have the equipment necessary to do such detailed glucose monitoring via a small sensor placed subcutaneously and connected to a recording device roughly the size of a pager. After downloading this device on a computer, this sensor can provide detailed glucose profiles for up to 72 hours of continuous glucose monitoring. Such information may be helpful in detecting hypoglycemia or hyperglycemia that would otherwise go undetected with conventional monitoring techniques. This data may then be used to make adjustments in the patient's diabetes self-management plan in order to optimize glucose control. This device is designed to supplement, rather than to replace, conventional self-monitoring of blood glucose.

1. Tests of Glycemia in Diabetics, *Diabetes Care*, Volume 27, Supplement 1, January 2004; pps S91-S93.
2. Goldstein DE et al., Tests of glycemia in diabetes (Technical Review). *Diabetes Care* 18:896-909, 1995.
3. Standards for Medical Care in Diabetes, *Diabetes Care,* Volume 27, Supplement 1, January 2004; pp S20.
4. Lee, Debra; Weiner, Sandy; Miller, Earl; A Study of Forearm versus Fingerstick Blood Glucose Monitoring, Supplement to the *Diabetes Educator,* Volume 27, Number 6, 2001.

10) TOBACCO-USE STATUS AND COUNSELING

- © Screen at time of initial diabetes diagnosis
- © Ask tobacco users about status of tobacco use at each visit.
- © Advise every tobacco user to quit
- © Assist every tobacco user who is willing to make a quit attempt access treatment.
- © Follow up with every tobacco user at every visit

Cigarette smoking is the leading cause of disease and premature death in the United States, and is responsible for over 440,000 deaths each year. People with diabetes who smoke are at increased risk of both macrovascular and microvascular complications. Smoking may also increase the risk of developing non-insulin dependent diabetes mellitus.

What questions should be included in an assessment?

All patients should be assessed for tobacco use at the time of diagnosis (Fig 10-1). Tobacco use cessation should be strongly recommended to any patient who uses tobacco. Those who use tobacco should be asked if they are willing to make a quit attempt.

Questions should include:

- Does the patient smoke, or do they use smokeless tobacco?
- Is the patient willing to make a quit attempt?

Those willing to make a quit attempt should be offered resources for that quit attempt. Those who are not willing should be encouraged to consider how quitting is personally relevant, and to identify the rewards of quitting as well as the risks of continuing.

How can a health-care provider help patients stop tobacco use?

Tobacco dependence is a chronic condition that often requires intervention. Effective treatments exist that can help the patient achieve permanent abstinence. Every patient who uses tobacco should be offered access to resources for counseling, and informed that pharmacotherapy doubles the success rate of quit attempts. Intervention is based on a patient's willingness to quit. Patients willing to try to quit should be referred to a counseling resource, and given information about the forms of effective pharmacotherapy (nicotine replacement therapy or Bupropion SR). (table 10-1)
http://www.surgeongeneral.gov/tobacco/

What smoking cessation information and programs are available in Vermont?

The Vermont Quit Line (1-877-YES QUIT or 1-877-937-7848) offers a range of services, from individual, pro-active telephone counseling to providing referrals to local cessation resources available in the community. The Vermont Association of Hospital and Health Systems (VAHHS) provides subsidized cessation programs through each of the hospitals in Vermont that include cessation groups and individual counseling.

Smokers can also find out if they are eligible for free or subsidized nicotine replacement therapy through the QuitBucks program or their managed care organization. Information regarding the QuitBucks program is available through the Vermont Quit Line or through the local VAHHS program.

1. The Renal Risks of Smoking, *Kidney International*, September 23, 1997 Vol.51; pps 1669-1677.
2. Fiore MC, Bailey WC, Cohen SJ, et. al. Treating Tobacco Use and Dependence. *Quick Reference Guide for Clinicians.* Rockville, MD: U. S. Department of Health and Human Services. Public Health Service. October 2000.
3. Smoking and Diabetes; *Diabetes Care*, Volume 27, Supplement 1, January 2004; pps S74-S75.
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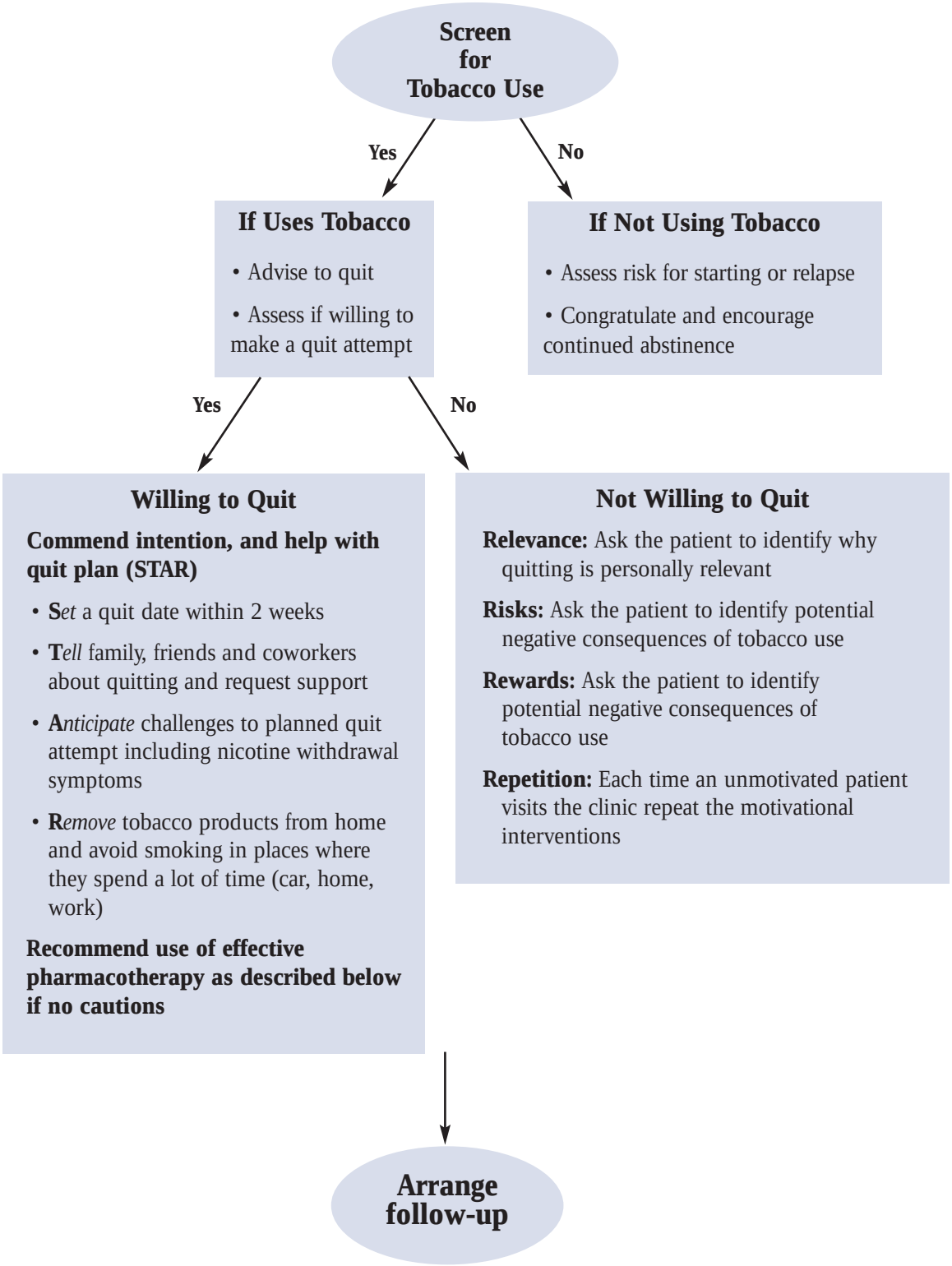
Screen for Tobacco Use
Yes
No
If Uses Tobacco
• Advise to quit
• Assess if willing to make a quit attempt
If Not Using Tobacco
• Assess risk for starting or relapse
• Congratulate and encourage continued abstinence
Yes
No
Willing to Quit
Commend intention, and help with quit plan (STAR)
• Set a quit date within 2 weeks
• Tell family, friends and coworkers about quitting and request support
• Anticipate challenges to planned quit attempt including nicotine withdrawal symptoms
• Remove tobacco products from home and avoid smoking in places where they spend a lot of time (car, home, work)
Recommend use of effective pharmacotherapy as described below if no cautions
Not Willing to Quit
Relevance: Ask the patient to identify why quitting is personally relevant
Risks: Ask the patient to identify potential negative consequences of tobacco use
Rewards: Ask the patient to identify potential negative consequences of tobacco use
Repetition: Each time an unmotivated patient visits the clinic repeat the motivational interventions
Arrange follow-up

Table 10-1: Adverse Effects, Cautions and Instructions on Pharmacotherapy

Types	Description	Advantages
1. Nicotine Gum *OTC*	Nicotine absorbed through the buccal mucosa by chewing on gum. Blood levels low and absorption slow	• Available OTC • May be useful for pts smoking < 10 cigs/d • Provides oral stimulation
2. Nicotine Patch *OTC*	Provides a steady blood level of nicotine through skin absorption	• Available OTC • Excellent compliance • Can be combined with gum
3. Nicotine Inhaler *Prescription*	A plastic two piece mouthpiece into which nicotine plugs are inserted that delivers nicotine to mouth	• Mimics hand to mouth and inhaling behavior • Can be used for cravings, problem times • No pulmonary absorption
4. Nicotine Nasal Spray *Prescription*	Device similar to a nasal steroid spray delivers 1 mg of nicotine to nasal mucosa	• Rapid high serum levels may help highly dependent
5. Nicotine Lozenge *OTC*	A lozenge in two dosage forms (2mg and 4mg) designed to dissolve in the mouth (not chewed or swallowed)	• Less jaw or dental problems than gum • More discreet, less objectionable than gum
6. Bupropion SR (Zyban) *Prescription*	Blocks uptake of neurotransmitters centrally. Substitutes for dopamine release from smoking.	• Non-nicotine • Pill form may improve adherence • Equally effective in pts without depression • Can be used with nicotine patch or gum or lozenge

Disadvantages	Dosage	Precautions
• Poorer adherence: • Low nicotine levels • Need to chew correctly • Hiccups, GI disturbances, jaw pain, orodental problems • Avoid acidic beverages	• 2 mg dose for <1 ppd • 4 mg dose for > 1 ppd • 10 –15 pieces/day (1-2 pieces/hour) • Taper over 10 weeks • Available in flavors	• < 18 yrs. • Unstable angina • Serious arrhythmias • Pregnancy (D)/nursing • Asthma (inhaler) • Nasal problems (spray) • Skin irritation, dermatitis (patch) • TMJ or dental problems (gum) • Hiccups, heartburn, cough (lozenge)
• Skin sensitivity and irritation • Insomnia or nightmares (can remove in evening to avoid)	Nicoderm CQ • 21 mg/d x 4 weeks • 14 mg/d x 2 weeks • 7 mg/d x 2 weeks Nicotrol • 15 mg/16h x 8 weeks	**NRT and Heart Disease** No significant adverse cardiovascular effects in healthy adults. Randomized clinical trials in stable patients with coronary artery disease do not indicate any short term adverse effects.
• Low nicotine levels: similar to nicotine gum • Throat irritation, coughing, oral burning • Low bioavailability at ≤50F • Avoid acidic beverages	• Pt inhales on mouthpiece as desired. One plug provides 80 inhalations • Use 6 to 16 plugs/day for 12 weeks then taper	**Ending NRT** Most individuals are able to stop using NRT without discomfort. The potential for dependence is low. Studies suggest there is little difference between forms of NRT when stopping them. NRT is tapered over 2 to 6 months.
• Initial nasal and throat irritation, rhinitis, sneezing, coughing • Headache • Side effects common	• One dose = 1 spray each nostril • One dose 1-5 times/hour or up to 40 times a day	
• Hiccups, heartburn, sore throat, coughing	• 2 mg dose for > 30 min to first cigarette in AM • 4 mg dose for ≤ 30 min to first cigarette in AM • 1 every 1-2hrs then taper over 6 months. Maximum 20/d	
• Rash, pruritus • Dry mouth, insomnia • Small risk of seizures • Drug interactions • Increased BP if both bupropion and patch used together	• Exclude current use of Bupropion (Wellbutrin) • Start one week before quit date • 150mg qd x 6 days then 150 mg BID for 2 mn • Reduce dose for renal and hepatic impairment	• Contraindicated in pts with h/o seizures, head trauma, anorexia, EtOH abuse • Pregnancy (B)/nursing • Avoid MAOIs, drugs that lower seizure threshold, caution with SSRIs, TCAs, antipsychotics, beta-blockers, cimetidine (label for others)

11) DIABETES MELLITUS AND EXERCISE

- © Exercise is an important therapeutic tool for people with diabetes.
- © Exercise programs should be individualized to maximize benefit and minimize risk.

Current opinion is that exercise is an important therapeutic tool for people with diabetes. Regular exercise can improve blood glucose control, reduce cardiovascular risk factors, increase weight loss, and improve overall health. In high risk individuals, exercise may delay or prevent the development of type 2 diabetes. However, the benefits and risks for each individual need to be identified and exercise programs need to be individualized.

Evaluating risk and prescribing exercise to minimize risk

Coronary artery disease

Patients with coronary artery disease should undergo an evaluation of exercise tolerance supervised by a physician with expertise in stress testing. Recommendations about appropriate exercise are dependent on the interpretation of exercise stress testing.

Patients at high risk for coronary artery disease and contemplating a moderate to maximal intensity exercise program should also undergo a graded exercise stress test. Any patient meeting one or more of the criteria should be considered at high risk: age >35 years; type 2 diabetes of >10 years duration; type 1 diabetes >15 years duration; microvascular disease; peripheral vascular disease; autonomic neuropathy; or presence of a non-diabetic risk factor for coronary artery disease (family history, cigarettes, etc.)

The need for an exercise stress test in patients interested in a low-intensity program is left to the clinical discretion of the prescribing clinician.

Peripheral vascular disease

Peripheral vascular disease can be detected by history and physical examination. Symptoms include intermittent claudication and cold feet. Signs include: decreased or absent peripheral pulses; cool feet; atrophy of subcutaneous tissues; and hair loss. Palpable dorsalis pedis and tibial pulses do not rule out ischemia of the forefoot. If there is any suggestion of compromise of blood supply to the forefoot or toes, quantitative toe pressure measurements and Doppler pressures at the ankle should be performed.

Consultation with a physician experienced in the care of patients with significant peripheral vascular disease may be necessary in order to design an appropriate exercise program.

Retinopathy

Annual dilated retinal exam is sufficient to identify patients with diabetic retinopathy. Because retinopathy may be associated with coronary artery disease; patients with retinopathy who intend to pursue moderate or intense exercise programs should undergo a graded cardiac exercise tolerance test.

If proliferative or moderate non-proliferative retinopathy exists, strenuous exercise should be avoided; particularly activities that substantially elevate blood pressure or involve jarring, (e.g. lifting heavy objects or any contact sport).

Nephropathy
Annual urine screening for proteinuria and microalbuminuria is sufficient to identify patients with nephropathy. Physicians should use their clinical judgement in tailoring exercise programs for such patients because nephropathy is a risk factor for coronary artery disease and definitive studies on the effect of exercise on the progression of overt nephropathy have not been done.

Peripheral Neuropathy
Peripheral neuropathy can be detected by physical examination. Signs of peripheral neuropathy include impairments in: deep tendon reflexes; vibratory sense; position sense; and sensation to touch. Strategies and exercises to improve balance may be useful for advanced cases of peripheral neuropathy.

Significant peripheral neuropathy is a contraindication to weight bearing exercise. Examples of non-weight bearing activities to recommend as alternatives include swimming, bicycling, rowing and arm exercises.

Autonomic Neuropathy
History and physical examination can detect autonomic neuropathy. Symptoms of autonomic neuropathy include: gastrointestinal symptoms; urinary system symptoms; and defective thermoregulatory capacity. Signs of autonomic neuropathy include abnormalities of skin color and abnormalities of body temperature.

Autonomic neuropathy may limit exercise capacity and may increase a patient's risk of a cardiovascular complication during exercise. Patients may have defective thermoregulatory capacities, thus they should be advised to avoid exercising in extreme temperatures and be attentive to their hydration status. Patients may be predisposed to hypotensive or hypertensive episodes following exercise.

Signs of cardiac autonomic neuropathy include resting tachycardia (>100 beats per minute) and orthostasis (>20 mmHg drop in systolic pressure on standing). Cardiac autonomic neuropathy is associated with sudden death and silent myocardial ischemia. Patients with cardiac autonomic neuropathy should be evaluated by a cardiologist prior to initiating an exercise program. Pulse and/or blood pressure monitoring may be recommended.

General recommendations about exercise programs

Program intensity
Moderate levels of exercise appear to be as beneficial as vigorous activity. Moderate level exercise programs may be easier for patients to follow.

Pre-exercise preparation
- Exercise should be avoided at time of peak insulin activity.
- To prevent increased insulin absorption, injections should be administered in body areas not involved with activity, e.g. abdomen.

- Patients using insulin should check their blood glucose levels before exercise.
- Patients should not exercise if fasting glucose levels are > 250 mg/dl and ketosis is present or if glucose levels are > 300 mg/dl, with or without ketosis.
- Pre-exercise carbohydrate intake may be necessary to avoid hypoglycemia.
- Pre-exercise carbohydrate should definitely be taken if pre-exercise glucose levels are < 100 mg/dl.
- Carbohydrate-based foods should be readily available during and after exercise.
- Proper warm-up and cool down period will decrease injuries.
- Diabetic ID bracelet or shoe tag should be worn.

Hydration

- Adequate hydration is necessary to maintain blood glucose levels and assure optimal cardiovascular function.
- Exercise in heat requires vigilant attention to hydration status.
- Pre-exercise hydration is particularly useful.
- Pre- and post-exercise body weight may be a useful guide for fluid replacement (conversion tables are available).

Foot care

People with diabetes should be encouraged to take precautions to avoid injury to their feet.

- Silica gel or air midsoles decrease impact.
- Polyester and cotton-polyester blend socks may be helpful in preventing blisters.
- Properly fitting footwear is very important.
- Patients should know to examine their feet closely for blisters before and after exercise.

Post-exercise routine

- Patients should monitor their blood glucose levels after exercise in order to learn their metabolic response to different exercise conditions.
- Post exercise hypoglycemia may occur up to 12 hours later, especially after prolonged or vigorous exercise.

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12) OBESITY TREATMENT AND MANAGEMENT FOR TYPE 2 DIABETES

- © Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes.
- © Weight loss and weight maintenance therapy should employ the combination of low-calorie diets, increased physical activity and behavior therapy.

What is the definition of obesity?

Obesity is defined as a Body Mass Index (BMI) of $\geq$ 30 kg/m^2 with overweight being a BMI of 25 to 29.9 kg/m^2.

What is the relationship between obesity and type 2 diabetes?

As many as 90 percent of individuals with type 2 diabetes are overweight or obese. Not only is there a strong association between the presence of obesity and the development of type 2 diabetes, but obesity also complicates its management. The presence of obesity exacerbates the metabolic abnormalities of type 2 diabetes, including hyperglycemia, hyperinsulinemia, and dyslipidemia. Obesity also increases insulin resistance, glucose intolerance and blood pressure, and ultimately may contribute to excessive morbidity and mortality in type 2 diabetes. There is strong evidence that even modest weight loss produced by lifestyle modification can reduce blood glucose and A1C levels in patients with type 2 diabetes.

What are the obesity treatment goals for people with type 2 diabetes?

Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Goals include:

- Reduce body weight.
- Reduce body weight by 5-10 percent from baseline.
- Weight loss from lifestyle modification is generally one to two pounds per week for a period of six months.
- Maintain a lower body weight over the long term (>1 year).
- Prevent further weight gain.

What is lifestyle modification?

The components of an effective lifestyle modification program include dietary modification, physical activity and behavior modification.

Can weight loss be maintained?

After successful weight loss, a program consisting of dietary therapy, physical activity and behavior therapy, which should be continued indefinitely, enhances the likelihood of weight loss maintenance.

A weight maintenance program should be a priority after the initial six months of weight loss therapy. The research suggests that a greater frequency of contacts between a patient and practitioner is predictive of long-term weight loss maintenance.

Are weight loss medications recommended?

While weight loss medications may be useful in the treatment of overweight persons with type 2 diabetes, their results, at best are modest and deemed effective only when used in conjunction with lifestyle modification. They are not indicated with BMIs of <27kg/m2 .

1. Nutrition Principles and Recommendations in Diabetes. *Diabetes Care*, Volume 27, Supplement 1, January 2004, pps S36-S46.

2. The Prevention and Treatment of Overweight and Obesity: Application to type 2 diabetes. *Diabetes Care* 1997:20. Supplement 1, pps 1744-1766.

3. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* NHLBI Obesity Education Initiative. NIH, NHLB, NHLBI, 2001, pps 1-78.

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13) IMMUNIZATION

- © Annual influenza vaccine is recommended for all patients with diabetes.
- © Pneumococcal vaccine is recommended for all patients with diabetes.

People with diabetes mellitus are six times more likely to be hospitalized during an influenza outbreak than those without diabetes. Pneumococcal infections cause 40,000 deaths annually in the United States; the highest mortality occurs among the elderly and patients with underlying medical conditions including diabetes. Many influenza and invasive pneumococcal infections are vaccine preventable.

Influenza vaccine

Annual vaccination is recommended in all patients with either type 1 or 2 diabetes. Split virus and whole virus vaccine preparations are available. The manufacturer's package insert should be reviewed for current year dose recommendations. The optimal time for vaccination in Vermont is October through mid November, but vaccination at any time during the winter offers benefit. Overseas travel plans may necessitate adjusting the vaccination schedule. Women with diabetes who will be in at least the 14th week of gestation during influenza season (December to March in the U.S.) should receive an influenza vaccine.

Contraindications

Known anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine contraindicates vaccination, unless there is a high risk of complications from influenza infection and appropriate allergy evaluation and desensitization has occurred. Moderate to severe acute illness is also a contraindication until symptoms have abated. The decision to administer the influenza vaccine for a patient with a history of Guillain-Barre Syndrome (GBS), especially if it occurred within six weeks of influenza vaccination, needs to be individualized in consultation with a vaccine expert. Mild illness with or without fever is not a contraindication. Vaccine manufacturer's package insert should be reviewed for product specific cautions and contraindications.

Concomitant administration of other vaccines

Influenza vaccine may be administered at the same time, at a different site, with other vaccines without increasing side effects or reducing efficacy. Specifically, influenza vaccine may be given at the same time as pneumococcal vaccine.

Pneumococcal vaccine

Pneumococcal vaccine is recommended in all patients with type 1 or type 2 diabetes at the time of diagnosis. The 23 capsular polysaccharide antigens in the current vaccine represent the pneumococcal serotypes causing 85-90 percent of invasive disease and the six serotypes most frequently causing invasive drug-resistant infection. Consult the manufacturer's package insert for dosage instructions.

Contraindications to pneumococcal vaccination
There is no contraindication to a first dose of pneumococcal vaccine other than moderate or severe acute illness. A severe allergic reaction to the pneumococcal vaccine is a contraindication to revaccination. Vaccine manufacturer's package insert should be reviewed for product specific cautions and contraindications.

The safety of 23 valent polysaccharide vaccine for pregnant women has not been studied. It should generally not be given to healthy pregnant women. Women who are at high risk of pneumococcal disease and who are candidates for pneumococcal vaccine should be vaccinated before pregnancy.

Revaccination
Routine revaccination of young, immunocompetent adults is not presently recommended. A single revaccination five or more years after the initial vaccination should be considered in 1) the elderly and 2) for those people with co-morbid conditions that put them at very high risk for invasive infection including asplenia, transplant, immunosuppression, and chronic renal failure.

Pediatric patients

Influenza vaccination
Infants with diabetes should not be immunized for influenza until they are > 6 months old. For children over the age of nine years who are receiving the influenza vaccine for the first time, two doses should be administered at least one month apart. The manufacturer's package insert should be reviewed for current year dose recommendations.

A live, attenuated, intranasal vaccine is now available for healthy people between the ages of 5 and 49 years. This vaccine is *contraindicated* for those with certain medical conditions, including *diabetes.*

Pneumococcal vaccination
All children with diabetes should receive a pneumococcal vaccine. Children who are < 24 months at the time of diagnosis should complete the initial series of the seven valent conjugated pneumococcal vaccine if the series has not been completed.

Children older than 24 months are potential candidates for both the 7 valent conjugated vaccine and the 23 valent polysaccharide vaccine. However, there is controversy over the sequencing and dosage for the two vaccines in this age group. Thus, it is advised that a physician with expertise in pediatric infectious disease be consulted about the best course of action.

The overarching principle is that all children with diabetes should receive some form of pneumococcal vaccine.

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2. CDC. Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recommendations and Reports.* April 04, 1997, 46(RR-08); 1-24.
3. *The Medical Letter.* September 10, 1999 / Volume 41; 82-81.

14) SCREENING FOR TYPE 2 DIABETES MELLITUS

- © Individuals who are at high-risk for type 2 diabetes should be screened for disease.
- © A fasting plasma glucose test (FPG) is the simplest and least expensive screening test.
- © A FPG result ≥ 126 mg/dl on two separate occasions is diagnostic of diabetes, values of 100-125 mg/dl are termed *impaired fasting glucose*, and values <100 mg/dl are considered normal.
- © Individuals with *impaired glucose tolerance*, can significantly reduce the risk of developing type 2 diabetes through intervention with diet and exercise, or Metformin.

Screening is recommended in high-risk individuals because type 2 disease is common, often asymptomatic in its early stages. and early detection and treatment can decrease the burden of illness. Approximately one-third of all people with diabetes are undiagnosed, and major risk factors are known which can identify high risk individuals.

Who are high-risk individuals?

Individuals with one or more major risk factors should be screened. No single risk factor is correlated with a 100 percent risk for type 2 disease. The greater the number of major risk factors present, the greater the risk of disease. The likelihood of diagnosing type 2 disease in a person with no risk factors is very low.

Major risk factors

- First degree relatives with diabetes (parents or siblings)
- Obesity (>20 percent over desired body weight or Body Mass Index (BMI *) > 25 kg/m2)
- Age greater than 45 years old
- Sedentary lifestyle
- Polycystic ovary syndrome
- Dyslipidemia (HDL cholesterol level < 35mg/dl (0.90 mmol/l) and/or triglyceride level > 250 mg/dl (2.82 mmol/l)
- Previously identified impaired fasting glucose or impaired glucose tolerance (see below)
- History of gestational diabetes or delivery of a baby over nine pounds
- Hypertension (> 140/90 mmHg)
- African-Americans, Hispanic Americans, Native Americans, Asian-Americans, Pacific Islanders

** Body Mass Index (BMI) = weight in kilograms/(height in meters)^2*

If the initial screening is negative, consider repeat screening every three years. Multiple risk factors or a high degree of clinical suspicion are indications for shorter intervals between screenings in certain individuals, and/or considering a more sensitive screening test such as a two-hour glucose tolerance test (see below).

What screening tests should clinicians use?

The *fasting plasma glucose test* (FPG) is the screening test preferred by the ADA for asymptomatic individuals because it is convenient and inexpensive. Fasting is defined as no consumption of food or caloric beverage for at least eight hours prior to testing.

The *oral glucose tolerance test* (OGTT) is also appropriate for screening, but is less convenient and more expensive than a FPG. The OGTT is a more sensitive test for type 2 diabetes and other states of impaired glucose metabolism, and should be considered when the FPG is negative, but the clinical suspicion for abnormal glucose metabolism is high. The DECODE study found that the two-hour value on OGTT correlated better with risk of both cardiovascular and all-cause mortality than did the FPG. *Data from the Diabetes Prevention Program indicates that individuals with impaired glucose tolerance, can significantly reduce the risk of developing type 2 diabetes through intervention with lifestyle changes.*

A *random plasma glucose* can be used as a non-diagnostic screening test. A random test is any plasma glucose test obtained without regard to the time since the meal. A level of > 160 mg/dl should be interpreted as abnormal and $\geq$ 200 is a provisional diagnosis of diabetes. A subsequent elevated FPG or OGTT result is needed to confirm the diagnosis of diabetes.

If an individual has *symptoms of diabetes* (increased thirst, increased urination, unexpected weight loss) and has a *random plasma glucose* $\geq$ 200 mg/dl, the diagnosis needs to be confirmed on a subsequent day by measurement of FPG, 2-h OGTT or a second random plasma glucose.

A1C is not recommended by the American Diabetes Association as a screening test because of inter-laboratory variability and the absence of established cut-off values for the normal range of results. Patients with diabetes may have normal A1C values, and such a result does not rule out diabetes. Elevated A1C results, although not diagnostic, are strongly suggestive of diabetes.

Whole blood glucose testing, finger stick or venous, is not recommended for screening or diagnostic testing. Results are usually 10-15 percent lower than plasma glucose levels and much less accurate if obtained by a home blood glucose monitoring device.

Interpretation of FPG and OGTT results

Screening test results fall into 3 categories: diabetic, impaired, or normal.

For fasting plasma glucose:

- Diabetic range is defined as FPG $\geq$ 126 mg/dl
- Impaired fasting glucose is defined as FPG $\geq$100 mg/dl, but < 126 mg/dl
- Normal fasting glucose is <100 mg/dl

For the OGTT:

- Diabetic range is defined as a two-hour post-load glucose value ≥ 200 mg/d.
- Impaired glucose tolerance is defined as two-hour values ≥ 140 mg/dl, but < 200 mg/dl
- Normal range is two-hour post-load value < 140 mg/dl

Action based on screening test results

An elevated result requires retesting on a different day to confirm the diagnosis. A second elevated result confirms the diagnosis of diabetes.

Impaired fasting glucose or *impaired glucose tolerance* are major risk factors for the development of diabetes. The interval between the next screening should be no greater than three years. Lifestyle treatment may be appropriate. *Intervention with diet and exercise, or Metformin, can significantly reduce the risk of developing type 2 diabetes.*

If test results are normal, the interval between the next screening should be no greater than three years if other major risk factors persist.

What medications can produce hyperglycemia and result in false positive screening results?

Glucocorticoids, furosemide, thiazides, estrogen containing products, ß-blockers, and nicotinic acid may produce hyperglycemia.

Screening is not recommended for type 1 disease

Screening for type 1 disease is not recommended because the incidence is too low to justify the expense, the interval between insulin failure and acute symptoms is short, there is no consensus on appropriate interventions for the "prediabetic" phase, and normal levels for autoantibodies related to type 1 disease have not been established. Screening for gestational diabetes is covered in a separate section of this manual.

1. Screening for Type 2 Diabetes, *Diabetes Care*, Volume 27, Supplement 1, January 2004; pps S11-14.
2. Standards of medical care in diabetes, *Diabetes Care*, Volume 27, Supplement 1, Jamuary 2004, pps S15-35.
3. Prevention or delay of type 2 diabetes, *Diabetes Care*, Volume 27, Supplement 1, Jamuary 2004, pps S47-54.
4. Diabetes prevention program research group: Reduction in the evidence of type 2 diabetes with life-style intervention or metformin. *NEJM*, Volume 346, 2002; pps 393-403.
5. Eastman RC, Cowie CC, Harris MI: Undiagnosed diabetes or impaired glucose tolerance and cardiovascular risk. *Diabetes Care*, Volume 20, 1997; pps 127-128.
6. The DECODE Study Group, the European Diabetes epidemiology Group: Glucose tolerance and cardiovascular mortality: comparison of fasting and 2-hour diagnostic criteria. *Arch Intern Med* 2001 Feb 12;161(3):397-405.

15) GESTATIONAL DIABETES MELLITUS (GDM)

- © Prenatal screening for GDM is important; however, there is controversy about whether screening should be universal or selective.
- © Women with GDM are at extremely high risk for developing type 2 diabetes later in life, and should be monitored closely.

Gestational diabetes mellitus (GDM) is defined as glucose intolerance that begins during pregnancy or is first recognized during pregnancy. The diagnosis is independent of whether management is limited to diet or requires insulin. It includes previously unrecognized glucose intolerance that predated pregnancy. Nationally, 4 percent of pregnancies are complicated by GDM. Based on the national prevalence, we can expect approximately 250 cases of GDM each year in Vermont.

Who should be screened

The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal Fetal Medicine have in the past recommended universal screening. Both Dartmouth Hitchcock Medical Center and the University of Vermont currently recommend and practice universal screening.

Patients at high risk for GDM should be screened at 12-16 weeks gestation, and then rescreened at 24-28 weeks, if the initial test is normal. Women at average risk should be screened at 24 -28 weeks of gestation. The ADA continues to not recommend screening for low-risk women. The definitions of these three risk groups are summarized in Table 15-1.

While there is no definitive answer to the question of whether universal or selective screening is optimal, many medical centers choose to employ universal screening due to the difficulty involved in adhering to a selective screening protocol in a busy practice. In addition, in states with similar racial profiles to Vermont, selective screening only results in a 15 percent reduction in the number of women screened. Universal screening is the more sensitive strategy, identifying nearly all women with GDM. Because of the high incidence of overt diabetes later in life, and the opportunity to provide counseling regarding life style at an early stage, missing the diagnosis of GDM may have long-term adverse effects.

What screening test result should be used as a threshold for subsequent diagnostic testing?

In the US, the current standard screening test is a 50-gram oral glucose load (either fasting or non-fasting) followed by a plasma glucose level one hour after the load.

In the recent past, the ADA recommended specifically that a screening result of 140 mg/dl warranted confirmation. In 2000 the ADA no longer recommended a specific threshold level, rather it suggested that a prudent threshold lies somewhere between 130 mg/dl and 140 mg/dl. A threshold of 140 mg/dl will miss 20 percent of women with GDM, whereas a threshold of 130 mg/dl will miss 10 percent of women with GDM. However, the more sensitive but less specific threshold of 130 mg/dl will result in more false positive results. For example, 25 percent of all patients will screen positive when a threshold

of 130 is used and will require a three-hour oral glucose tolerance test.

The obstetrics service at the University of Vermont currently uses 135mg/dl as a screening threshold. Dartmouth Hitchcock Medical Center is using 140 mg/dl as a screening threshold.

The ADA suggests that administering a fasting 100-gram three-hour oral glucose tolerance test (OGTT) as an initial test may be appropriate in high risk individuals or in high risk populations.

Confirmation of the diagnosis

Confirmation of the diagnosis of GDM requires that two or more of the four plasma glucose values obtained during a fasting 100-gram three-hour oral glucose tolerance test (OGTT) be elevated. In 2000 the ADA adopted the Carpenter-Coustan definitions for the upper limits of normal for OGTT values (see Table 15-2). These thresholds are used by the University of Vermont and Dartmouth Hitchcock Medical Center.

Table 15-1

Upper limits of normal for OGTT

Plasma glucose	Carpenter-Coustan (UVM/DHMC)
Fasting	95 mg/dl
1-hour	180 mg/dl
2-hour	155 mg/dl
3-hour	140 mg/dl

Prenatal monitoring of a woman with GDM

Glycemia

Daily self-monitoring of blood glucose (SMBG) is superior to intermittent office monitoring of plasma glucose. For women treated with insulin, postprandial monitoring is superior to preprandial monitoring. Urine glucose monitoring is not useful.

Ketonemia

Urine ketone monitoring may be useful in detecting inadequate caloric or carbohydrate intake in women treated with calorie restriction.

Hypertensive disorders

Serial blood pressure measurement is recommended. Serial urine protein measurement is recommended if hypertension exists.

Fetal well-being

Increased monitoring of fetal well-being is indicated if fasting blood glucose levels are > 105 mg/dl or the pregnancy is post-term. The specific monitoring technique employed, the time of initiation of the monitoring and the frequency of the monitoring are dependent on the uniqueness of each patient and the cumulative fetal risk from GDM and other medical/obstetric conditions.

Asymmetric Fetal Growth
Ultrasound measurement of fetal abdominal girth may be helpful in detecting women whose infants are at increased risk for macrosomia. Detection of asymmetrical growth, particularly during the third trimester, may identify fetuses that would benefit from maternal insulin therapy. Macrosomic fetuses are a risk factor for shoulder dystocia and Cesarean section.

Treatment of GDM

Diet and Exercise
All women with GDM should receive individualized medical nutrition therapy by a registered dietitian consistent with current ADA recommendations. Obese women (BMI > 30) whose caloric intake is reduced 30-33 percent (~ 25 kcal/kg actual weight per day) experience reduced hyperglycemia and lower triglyceride levels. Active lifestyles should be encouraged. Moderate exercise has been shown to lower maternal glycemia.

A 1998 study by Major et al.[7] showed that restriction of carbohydrates to 35-40 percent of total calories decreased maternal glucose levels and improved maternal and fetal outcomes.

Pharmacologic therapy
Insulin is the pharmacologic therapy that has most consistently been shown to reduce fetal morbidity when used in conjunction with medical nutrition therapy. The ADA recommends initiating pharmacologic therapy when medical nutrition therapy fails to keep fasting whole blood glucose levels < 95 mg/dl, one-hour postprandial whole blood glucose levels < 140 mg/dl, or two-hour postprandial whole blood glucose level < 120 mg/dl. The goal of therapy is to maintain maternal glycemia below the above cut-off levels. If insulin therapy is employed, human insulin should be used. Medication doses should be determined by whole blood finger stick measurements. Postprandial whole blood finger stick measurements are superior to preprandial measurements.

Currently oral glucose-lowering agents are not generally recommended for use during pregnancy. Glyburide is not FDA approved for the treatment of gestational diabetes. The ADA feels that further studies are needed to establish its safety.

Postpartum evaluation

The ADA recommends that all women with GDM should be screened for glucose intolerance six weeks after delivery. Those women with a greater degree of glucose impairment during pregnancy have the greatest risk for persistence of glucose intolerance postpartum. All women with a history of GDM should be educated regarding lifestyle modifications and the risk of developing insulin resistance.

If postpartum glucose levels are normal, subsequent serial evaluation of glycemia should occur at a minimum of three year intervals.

If the results at six weeks postpartum show impaired fasting glucose or impaired glucose tolerance, patients should be retested annually. These individuals should receive intensive medical nutrition therapy and prescribed individual exercise programs because of their very high risk of developing diabetes. Referral to practitioners with expertise in the education and care of adult diabetes is appropriate for women with postpartum impaired glucose levels.

Patients with abnormal postpartum glucose levels should be referred to practitioners with expertise in the management of diabetes.

Postpartum education

Diet and Exercise

Women should be encouraged to maintain a normal body weight with a regimen of medical nutrition therapy and exercise in an effort to reduce insulin resistance.

Medications

Medications that increase insulin resistance (e.g. glucocorticoids and nicotinic acid) should be avoided if possible. GDM is not a contraindication to the use of low dose estrogen-progestogen oral contraceptives.

Symptoms of hyperglycemia

Women should be educated about the symptoms of hyperglycemia and encouraged to seek medical attention with the advent of symptoms.

Family planning and future pregnancies

Family planning should be encouraged to assure optimal glycemia monitoring and regulation in subsequent pregnancies.

Implications for offspring

Women should be advised of the need for their offspring to be monitored for the development of obesity and glucose intolerance.

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16) MEDICATIONS

- © Medication Therapy can involve oral agents, insulin, or a combination of these two therapies.
- © Medication Therapy is a therapeutic tool for use in lowering and maintaining blood glucose levels.

Why use Medication Therapy?

Results from the United Kingdom Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complication Trial (DCCT) conclusively revealed that lowering blood glucose reduces the risk of developing complications. Medication Therapy is a potential therapeutic tool for use in accomplishing this goal.

What is Combination Therapy?

Combination Therapy is the use of two or more oral agents or an oral agent combined with insulin. Current research based opinion indicates that combination therapy is an effective tool for the medical treatment of diabetes. An additive effect is observed on glycemic goals when combination therapy is utilized.

The choice of insulin use, type and dosage must be individualized and balanced to allow flexibility in lifestyle choices. It requires an integrated approach balancing lifestyle, nutrition, medical nutrition therapy, and exercise.

What are the issues to consider when using Medication Therapy?

- Weight gain may be seen as a side effect of oral agent therapy, however it is often seen concomitant with improved control.
- Due to risks for hypoglycemia, as glycemic control improves, oral agents and/or insulin doses may need to be adjusted.
- All insulin may cause hypoglycemia if dose, nutrition and exercise are not synchronized.
- Glargine (Lantus) insulin is a clear, peakless insulin with a 24+-hour duration. *Glargine is not to be mixed with any other insulin or solutions!*
- Ultralente insulin has variable absorbtion and peaks due to individual variability.
- Insulin action (absorption and duration) may be variable for different people.
- The mixing of appropriate insulins and/or multiple daily injections can improve blood glucose levels.
- As a general rule, the mixed insulins should be of the same brand.
- Regular or Lispro insulins should be drawn up before the longer acting insulins to prevent contamination of the faster acting insulin, leading to efficacy variance.

How do the Oral Agents compare with one another?

Medication	Action	Prescribing Considerations
BIGUANIDES		
Metformin (Glucophage, Glucophage XR, Metformin ER)	*Decreases production of glucose in liver, enhances insulin sensitivity by increasing peripheral glucose uptake and utilization.*	• Start at low dose, titrate up. • GI symptoms: Diarrhea, nausea, vomiting, abdominal bloating, flatulence and anorexia most common side effects. These symptoms are generally transient and resolve spontaneously during continued treatment. Taking with food and/or temporarily reducing the dose may be helpful. • May have positive effects on triglycerides, total cholesterol and LDL. • Contraindicated in men with serum creatinine 1.5 or in females with 1.4 or greater. • Contraindicated with hepatic dysfunction. • Contraindicated in acute or chronic lactic acidosis. • Generally not indicated during pregnancy, breastfeeding or in children. • Should be temporarily withheld in situations of cardiovascular collapse, acute MI, acute exacerbation of CHF, use of iodinated contrast media and with a major surgical procedure. • Do not use in patients with excessive alcohol use. • May be contraindicated in patients with CHF. • Requires 2-11 weeks of use before determining effectiveness. • Refer to packaging label for additional prescribing considerations.

Medication	Action	Prescribing Considerations
THIAZOLIDINEDIONES (GLITAZONES)		
Rosiglitazone (Avandia) **Pioglitazone (Actos)**	*Improves insulin sensitivity within peripheral muscle and adipose sites. Inhibits hepatic gluconeogenisis*	• Requires 2-16 weeks of use before determining effectiveness. • Check LFTs before start, and every two months thereafter for the next 12 months. Should not be initiated if patient has active liver disease or increased ALT >2.5 times normal. • Rosiglitazone may increase HDL and LDL. • Pioglitazone decreases triglycerides and increases HDL. • May cause weight gain and fluid retention. • Use with caution in patients with hepatic disease or with advanced heart disease. • Generally not indicated during pregnancy, breastfeeding or in children. • Decreases oral contraception effectiveness and may cause resumption of ovulation in anovulatory women. • Refer to packaging label for additional prescribing considerations.

Medication	Action	Prescribing Considerations
ALPHA-GLUCOSIDASE INHIBITORS		
Acarbose (Precose) **Miglitol (Glyset)**	• *Delays digestion of carbohydrates, lowers rise in post-meal blood glucose.*	• To be taken with first bite of food. • GI symptoms are the most common reaction. The incidence of diarrhea and abdominal pain tend to diminish with continued treatment. • Reduces bioavailability of Digoxin, Propanolol, Ranitidine, digestive enzymes • Avoid use in patients with GI disorders. • Avoid use of Acarbose in patients with creatinine > 2. • Avoid use of Acarbose in patients with cirrhosis. • Neither agent recommended in patients with creatinine clearance <25mL/min. • Generally not indicated during pregnancy, breastfeeding or in children. • Must use dextrose (not sucrose) to correct hypoglycemia when taking Acarbose. • Refer to packaging label for additional prescribing considerations.

Medication	Action	Prescribing Considerations
MIXTURES		
Avandamet		• See Avandia and Metformin
Metaglip		• See Metformin and Glipizide
Glucovance		• See Glyburide and Metformin

Medication	Action	Length of Action	Prescribing Considerations
SULFONYLUREAS			
Glyburide (Diabeta) (Micronase) (Glynase)	*Stimulates insulin release from the pancreas.*	12-24 hours	• Hypoglycemia, gastrointestinal complaints and weight gain are most common side effects. • Contraindicated in patients with diabetic ketoacidosis, severe infection, surgery, or trauma. • Avoid use in patients with significant alcohol use. • Generally not indicated during pregnancy, breastfeeding or in children. • Refer to packaging label for additional prescribing considerations.
Glipizide (Glucotrol) (Glucotrol XL)		12-16 hours	
Glimepride (Amaryl)		24 hours	

Medication	Action	Length of Action	Prescribing Considerations
MEGLITINIDES			
Repaglinide (Prandin)	*Stimulates insulin release from the pancreas. Insulin release is glucose dependent and diminishes at low glucose concentrations.*	2-3 hours	• Administer 15 to 30 minutes before meals. (5 minutes before meals for Starlix) • Only works with the presence of glucose. • Approved for combination use with Metformin only. • Use Repaglinide cautiously in patients with hepatic impairments. • Repaglinide contraindicated in patients with diabetic ketoacidosis, severe infection, surgery, or trauma. • Generally not indicated during pregnancy, breastfeeding or in children. • Refer to packaging label for additional prescribing considerations.
Nateglinide (Starlix)		4 hours	

How do the insulins compare with one another?

Insulin type	Onset of Action	Time of Peak	Duration of action
Rapid Acting Analogs			
Aspart (Novolog)	5 – 15 minutes	½ - 1½ hours	3 - 5 hours
Lispro (Humalog)	10 – 15 minutes	½ - 1½ hours	3 - 4 hours
Short Acting			
Human Regular	30-60 minutes	2 - 4 hours	8 - 12 hours
Intermediate Acting			
Human NPH	1½ hours	4 - 12 hours	24 hours
Human Lente	2 – 5 hours	7 - 15 hours	24 hours
Long Acting			
Human UltraLente	4 – 8 hours	10 - 30 hours	18 - 30 hours
Basal			
Glargine (Lantus)	1½ hours	peakless	24 hours
Pre-Mixed			
Humalog Mix 75/25 NPL/Lispro	10 minutes	½ - 4 hours	24 hours
Human 70/30 NPH/R or 70 aspert protamine suspension/ 30 aspart (depending on the brand)	10 minutes	2 - 12 hours	24 hours
Human 50/50 NPH/R	30 minutes	1 - 6 hours	14 + hours

When should aspirin be used?

The ADA is recommending that aspirin therapy (75-162 mg/day) be used as a primary prevention strategy in people with type 1 or type 2 diabetes who are at increased cardiovascular risk, including those over 40 or who have other cardiovascular risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). They are also recommending the use of aspirin therapy for all people with diabetes who have a history of myocardial infarction, vascular bypass procedure, stroke, transient ischemic attack, peripheral vascular disease, claudication, and/or angina, as secondary prevention.

Patients under the age of 21 should not use aspirin therapy because of the increased risk of Reye's syndrome. People with bleeding disorders or aspirin allergies should avoid aspirin therapy as well.

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2. *Physicians Desk Reference;* Medical Economics Company, Inc.; 2001.

3. *2002 Drug Facts and Comparisons;* 56th edition.

4. Aspirin Therapy in Diabetes, *Diabetes Care,* Volume 27, Supplement 1, January 2004; pps S72-S73.

17) INTENSIVE INSULIN MANAGEMENT

- © Candidates for Intensive Insulin Management must be motivated to improve glucose control and be able to assume responsibility for their day-to-day care.
- © Use of Intensive Insulin Management should be initiated, monitored and supported by a Comprehensive Diabetes Team.
- © Intensive Insulin Management is essential during pregnancy and recommended for all who wish to reduce their risk of diabetes complications.

The challenge of treating type 1 diabetes is to mimic physiologic insulin action. Optimal glycemic control demands that the right insulin be given at the right time and in the right amount. New insulins and new insulin delivery devices allow better basal and bolus insulin replacement than ever before.

What is Intensive Insulin Management?

Intensive Insulin Management is the strategy of making multiple adjustments in insulin dosage each day in order to achieve better glucose control with less hypoglycemia, less hyperglycemia, and more lifestyle flexibility. This strategy is encouraged for most people, primarily for people with type 1 diabetes, and is often the only means of achieving an ideal level of glucose control in these patients without excessive and unsafe episodes of hypoglycemia.

The major emphasis is on making frequent adjustments in rapid- or short-acting insulin dosages. The dosage of regular insulin, lispro insulin (Humalog) or insulin aspart (NovoLog) is typically altered based on the pre-meal blood glucose level, carbohydrate content of the meal, and the anticipated level of physical activity. In addition, an individualized correction factor, or insulin sensitivity factor, is used to determine the dose needed to reduce an elevated blood sugar level. This method of insulin dosing can be tailored to fit almost any lifestyle. The two methods of insulin delivery for Intensive Insulin Therapy are Continuous Subcutaneous Insulin Infusion (CSII) or an insulin pump, and Multiple Daily Injections (MDI).

How is this different from Conventional Insulin Management?

Conventional insulin regimens usually consist of only two insulin injections per day using a mixture of short-acting and intermediate-acting insulins (such as regular and NPH). The dose is usually identical every day, and requires patients to be very consistent about meal times, meal content, and timing and duration of any strenuous activity. The use of a sliding scale is also considered Conventional Insulin Management, as it reacts only to the current blood glucose level without regard for meals. Conventional Insulin Management rarely allows achievement of A1C goals, commonly results in hypo- and hyperglycemia, demands extra snacking, and requires the patient's lifestyle to revolve around his or her insulin schedule.

Learning how to adopt an Intensive Insulin Management plan is complex and ideally involves the instruction and support of a comprehensive diabetes team. This team often includes the following:

- a registered dietician skilled in teaching the counting of carbohydrates to accurately estimate meal content.
- a diabetes nurse educator who can instruct patients in proper self-monitoring of blood glucose, insulin administration, insulin action times, insulin to carbohydrate ratios, and correction factors.
- an endocrinologist or other physician skilled in the use and adjustment of intensive insulin regimens utilizing various combinations of insulin types, timing, and delivery devices such as insulin pumps.

What are some examples of Intensive Insulin Management?

The following are examples of some common intensive insulin regimens:

Continuous Subcutaneous Insulin Infusion (CSII)
Patients utilizing this insulin delivery method wear a continuous subcutaneous insulin infusion pump worn 24 hours per day (it can be disconnected for short periods of time such as bathing). The pump exclusively delivers rapid-acting insulin such as lispro insulin or insulin aspart as basal and bolus insulin.

Multiple Daily Injections (MDI)
This regimen consists of multiple injections of insulin, three or four times per day, using a combination of rapid- or short-acting, and either long-acting or intermediate-acting insulin. Three typical therapeutic regimes are:

- Glargine insulin (Lantus) once a day as a fixed dose (titrated to achieve pre-meal blood glucose in the target range) in combination with lispro insulin, insulin aspart, or regular insulin with each meal (variable dose as described above titrated to achieve post-meal blood glucose in the target range)
- NPH or Ultralente insulin at bedtime as a fixed dose in combination with lispro insulin, insulin aspart, or regular insulin with each meal (variable dose as described above)
- NPH or Ultralente at breakfast and supper (or bedtime) as a fixed dose in combination with lispro insulin, insulin aspart, or regular insulin with each meal (variable dose as described above).

Are there unique benefits to Insulin Pump (CSII) Therapy over Multiple Daily Injections (MDI)?

There are several reasons people with diabetes may find an insulin pump provides better outcomes and more lifestyle flexibility than multiple daily injections. Frequently reported benefits include:

- Less variation in insulin absorption (about 3% vs. 25%) due to exclusive use of rapid- or short-acting insulin, single injection site and eliminating subcutaneous depot of insulin.
- Fewer insulin injections (the subcutaneous catheter is replaced every two or three days rather than three to four injections each day).

- Can be programmed to more closely mimic normal pancreatic insulin secretion patterns (to accommodate working variable shifts, physical activity, nocturnal hypoglycemia, the "dawn phenomenon", unpredictable lifestyle, high fat meals, etc.).
- May easily take a small bolus with snacks.
- Can deliver insulin boluses accurately in 1/10 unit increments (rather than one or two unit increments as with conventional syringes). This is particularly important in very insulin sensitive patients including young children.

Can Intensive Insulin Therapy be used for people with type 2 diabetes?

People with type 2 diabetes who are unable to achieve target blood glucose levels with diet, exercise and oral diabetes medications would benefit from intensive insulin management. Insulin requirements are larger in type 2 diabetes because of the insulin resistance, yet the principles of treatment are otherwise the same.

Are there patients in whom Intensive Insulin Therapy is not feasible or not appropriate?

As with any therapy, there are people in whom Intensive Insulin Therapy is not a practical or appropriate strategy. This may include patients with limited insight and judgment, those who cannot accurately monitor their blood glucose or estimate carbohydrate content, and patients who are not likely to benefit from improved glucose control. Intensive Insulin Therapy may be unsafe in patients with hypoglycemia unawareness. In the DCCT, the most common side effects of Intensive Therapy were a three-fold increase in severe hypoglycemic reactions and weight gain. Many patients with type 2 diabetes are less prone to hypoglycemia and can achieve good glycemic control on less intensive insulin regimens.

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18) PSYCHOSOCIAL ISSUES IN DIABETES CARE

- © Assess key psychosocial factors affecting chronic care.
- © Choose appropriate behavioral strategies to enhance diabetes management.

One of the biggest struggles for both patients and practitioners is identifying, addressing and accomplishing the behavioral changes necessary to achieve the best possible diabetes management in their daily lives. Best medical practice requires practitioners to incorporate both the "science" and "art" of behavior change. There is a wealth of research in the behavioral science literature on factors that lead to best outcomes in diabetes management.

What does psychology have to do with diabetes care?

Diabetes interventions are predominantly "behavioral." The delivery of successful medical care for individuals with diabetes ultimately depends on their ability to "self-manage." Over time, the behavioral science literature reviews and position statements have consistently shown that:

- People of all ages have difficulty following diabetes regimens.
- People can do well with some aspects of their care while having extreme difficulty with other aspects of care.
- Children and adults living with diabetes have the most difficulty with the following, in order:
  1) diet
  2) exercise
- Timing and adjustment of diabetes medications is difficult, and can result in adherence issues.
- Miscommunication between patients and providers on important aspects of diabetes care is an ongoing issue.

It is important to remember that A1C results are often a poor indicator of patient behavior. A1C levels do not always correlate with adherence to behavioral interventions and therefore can be misleading. Fluctuations in A1C can be due to a variety of factors including hormonal changes, stress, growth and development, and physical health status.

Psychiatric co-morbidity

Depression

- has a high rate of co-morbidity with diabetes (rates range from 15-40 percent).
- may be more severe for people with diabetes
- has an adverse effect on A1C control and self-care
- is often undiagnosed and untreated

- can be treated with psychotherapy and/or psychopharmological agents

Anxiety

- appears to be more prevalent in people with diabetes than the general population
- can be treated with psychotherapy and/or psychopharmological agents

Eating disorders (*anorexia nervosa and bulimia nervosa*)

- appear to be more common in people with diabetes than the general public
- may be more severe for people with diabetes
- have an adverse effect on diabetes control

Care teams should have a clear plan for assessing and responding to identified psychiatric co-morbidities and psychosocial problems.

What are the key psychosocial factors affecting chronic care?

Best practice looks at assessing the "whole person" to assess where potential strengths and weaknesses with the diabetes regime are likely to occur. Assessment should include, but is not limited to, the following areas:

In pediatric patients

- Developmental stage
- Temperament
- Parent-child issues
- Family dynamics
- Extended family/support
- Cognitive/school issues

In adult patients

- Role of significant others (helpful, hurtful)
- Role of family of origin
- Diabetes at work and play
- Psychological factors/ predictors of poor adjustment

Treatment issues across the ages

- Personality
- Natural/acquired coping skills
- Psychiatric history (patient, family)
- Substance use/abuse
- Cultural factors
- Overall "quality of life"

- Weight history/genetics
- Struggles with adherence
- Meal planning
- Exercise
- Peer issues
- Diabetes provider burnout
- Financial stress of patient and family

What behavioral strategies enhance diabetes management?

- Set realistic goals: Collaboration is key!
- Work *with* the family to resolve team issues and support the patient
- Adopt an educational model of patients as "continuous learners".
- Individualize treatment to fit strengths/weaknesses of patient/family, including assessing individual patient "coping style".
- Incorporate "empowerment" approaches to enhance patient's "self-efficacy" (i.e., patient successfully targeting and accomplishing a particular goal.)
- Assess readiness for behavior change using 5A's:
    - *Acceptance (of the disease)*
    - *Adjustment (that needs to be made for effective self care and disease management)*
    - *Acquisition of skills (necessary to succeed)*
    - *Adoption (of new skills in specific life scenarios)*
    - *Activation (of changes)*
- Avoid "punishing" and/or "shaming" patients for diabetes mismanagement. Arrange for other provider care when a bad 'fit' between patient and provider exists.
- Practice good communication skills and advocate the same for communication between patient and family members.
- Practice a "problem solving" approach and teach patient and family members this as a strategy. (What does the patient perceive as the barriers to more effective management? What are alternative choices?)
- Assess and enhance community supports (medical, school, work, social, religious) including, but not limited to, formal support groups specific to diabetes patients and families.

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19) PRIMARY PREVENTION

- © Counsel people at high risk for the development of diabetes on the benefits of moderate weight loss and exercise (weight loss of 5-7% with 150 minutes of exercise per week)
- © Screen people at high risk
- © Monitor people with pre-diabetes for the development of diabetes every 1-2 years
- © Based on current knowledge, the American Diabetes Association (ADA) does not support the routine use of drug therapy in the prevention of Type 2 diabetes.

Preceding chapters have focused on the treatment of the signs and symptoms of diabetes, and on the prevention or delay of disease related complications. Screening, testing, improved nutrition, weight control, exercise, smoking cessation and a variety of medications can be used to accomplish these goals. This chapter looks at preventing or delaying the development of diabetes.

How are prevention and treatment different?

While both prevention and treatment of diabetes are ultimately intended to reduce related complications, there are primary differences. Dr. Allen Spiegel, director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), has stated *"Every year a person can live free of diabetes means an added year of life free of the pain, disability, and medical costs incurred by this disease..."*.[1]

People with diabetes:

1. will undergo tests and procedures to detect the development of complications,
2. are at increased risk for acute macrovascular complications and progressive microvascular complications,
3. have more rigorous goals for B/P and lipid management, and
4. risk social and economic discrimination.[2]

Primary prevention is designed to change behaviors that cause a risk to health before the illness occurs.[3] In other words, we want to prevent or delay the development of not just the complications of diabetes, but of diabetes itself.

Why is primary prevention important?

Currently, 24 percent of the people in the United States, roughly 47 million adults, are affected by metabolic syndrome.[4] Sixteen million people in the United States between the ages of 40 and 74 have pre-diabetes.[5] An increasing number of children and adolescents are being diagnosed with pre-diabetes, with obese girls more likely than their male counterparts to suffer from this medical condition.[6]

In the past ten years, the number of Americans diagnosed with diabetes has increased by 61 percent, and that number is expected to double by the year 2050. This corresponds with an increase in inactivity and obesity that experts believe is directly linked to the increase in pre-diabetes and diabetes.[7] People with a BMI of 30 or greater are at five times greater risk of developing diabetes compared to those people with a BMI of 25 or less.[8]

Treatment of diabetes may prevent or delay some of its most devastating complications but in most cases treatment cannot restore normal glycemic control, or prevent all adverse effects.[9] Diabetes is the sixth leading cause of death among adults in the United States.[10] Primary prevention is the preferable alternative.

What is metabolic syndrome?

Metabolic syndrome exists when a person exhibits three or more of the following risk factors: waist measurement more than 40 inches (men) or 35 inches (non-pregnant women); HDL less than 40 (men) or 50 (women); blood glucose levels equal to or greater than 110; triglycerides equal to or greater than 150; blood pressure equal to or greater than 130/85. People with metabolic syndrome are at increased risk for the development of diabetes, and heart disease.[11]

What is pre-diabetes?

Impaired glucose tolerance (IGT) is an intermediate stage between normal glucose tolerance and overt diabetes[12] referred to as pre-diabetes. Pre-diabetes is defined as a two-hour value on an oral glucose tolerance test (OGTT) greater than or equal to 140mg/dl but less than 200, or a fasting plasma glucose test (FPG) result of greater than or equal to 100mg/dl but less than 126mg/dl. A serious medical condition, it is believed that much of the long-term damage to the cardiovascular system may be occurring during the pre-diabetic stage.[13]

Can we prevent diabetes?

The Diabetes Prevention Program (DPP) has shown conclusively that changes in diet and exercise level can delay or prevent the development of type 2 diabetes. The trial included 3,234 people with IGT, of diverse racial and ethnic backgrounds. The lifestyle interventions were found to be effective in all participants, regardless of gender, age, or ethnic background. The study determined that a program of 150 minutes of moderate physical activity per week, combined with a loss of seven percent of body weight could decrease a person's risk of developing type 2 diabetes by 58 percent.

A separate study, the Finnish Diabetes Prevention Study also demonstrated a 58 percent reduction in risk with lifestyle intervention. Interventions included 150 minutes of moderate exercise per week and a five percent reduction in body weight.[14]

Small things matter when looking at lifestyle changes. The risk of developing type 2 diabetes increases by 14 percent for every two-hour period of time spent watching television during the day. By replacing those two hours of television viewing with moderate activity within the home, a person can decrease the risk of developing obesity by nine percent and the risk of developing diabetes by 12 percent.[15]

Those individuals treated with metformin during the DPP decreased their risk of developing type 2 diabetes by 31 percent. In individuals 22-44 years of age, with a BMI > 35 kg/m2, metformin was as effective as lifestyle changes in preventing Type 2 diabetes. Two additional studies, the TRIPOD and the STOP-NIDDM, looked at the use of troglitazone and acarbose, respectively, in the prevention of type 2 diabetes. The TRIPOD demonstrated a 56 percent reduction in diabetes development with troglitazone, while the STOP-NIDDM study demonstrated a 36 percent reduction in risk with acarbose.

None of the medications tested demonstrated prevention against CVD, and all of the medications require routine monitoring and have significant potential side effects. *Based on current knowledge, the ADA does not support the routine use of drug therapy in the prevention of type 2 diabetes.*

Where should we focus our prevention efforts?

- Counsel people at high risk for the development of diabetes on the benefits of moderate weight loss and exercise (weight loss of 5-10% with 150 minutes of exercise per week) and behavior modification techniques.
- Screen all individuals 45 years of age or older, particularly those who are overweight or obese (BMI > 25kg/m2) for pre-diabetes as part of a health care office visit. The ADA also suggests that those individuals less than 45 years of age with one or more risk factors should be screened. (Table 1)
- Rescreen individuals with normoglycemia every 3 years.
- Monitor and treat for other CVD risk factors.
- Provide follow-up counseling.
- Rescreen individuals with pre-diabetes every 1-2 years.

Table 1

Major risk factors

- First degree relatives with diabetes (parents or siblings)
- Overweight (Body Mass Index (BMI *) > 25 kg/m^2)
- Age greater than 45 years old
- Sedentary lifestyle
- Polycystic ovary syndrome
- Dyslipidemia (HDL cholesterol level < 35mg/dl (0.90 mmol/l) and/or Triglyceride level > 250 mg/dl (2.82 mmol/l)
- Previously identified impaired fasting glucose or impaired glucose tolerance
- History of gestational diabetes or delivery of a baby over nine pounds
- Hypertension (> 140/90 mmHg)
- History of vascular disease
- Race/ethnicity (African-Americans, Hispanic Americans, Native Americans, Asian-Americans, Pacific Islanders)

**Body Mass Index (BMI) = weight in kilograms/ (height in meters squared)*[16]

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